Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

06 September, 2018 at 10:00 at Avonmouth House, SE1 6NX

Present:

Name	*Present*	*Notes*
Professor William Bernal	Yes	
Dr Tony Calland MBE	Yes	Chair
Professor Barry Evans	Yes	
Dr. Liliane Field	Yes	
Mr. Myer Glickman	Yes	
Mr Anthony Kane	Yes	Lay
Professor Jennifer Kurinczuk	Yes	
Mr Andrew Melville	Yes	Lay
Mrs Diana Robbins	Yes	Lay
Dr Murat Soncul	Yes	Alternate Vice Chair (Agenda Item 5.a. – conflict declared)
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Miss Kathryn Murray	Senior Confidentiality Advisor

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introductions

The Chair introduced Dr Liliane Field and Mr Myer Glickman, recently appointed Members to the CAG.

Declarations of Interest

- 18/CAG/0133

Dr Murat Soncul, Alternate Vice-Chair, declared an interest in this application as his employer was named on the application. The CAG agreed that Dr Soncul should not be present for the consideration of the item or participate in the advisory recommendation.

2. APPROVAL DECISIONS

Secretary of State for Health and Social Care Approval Decisions

The DH senior civil servant on behalf of the Secretary of State for Health and Social Care (SofS) agreed with the advice provided by the CAG in relation to the 05 July 2018 CAG meeting applications.

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the 05 July 2018 CAG meeting applications.

3. AMENDMENTS – Non-Research

a. ECC 6-02 (FT3)/2012 - Sentinel Stroke National Audit Programme

Context

Purpose of application

The Sentinel Stroke National Audit Programme (SSNAP) is hosted at King's College London and commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England and the Welsh Government and has been operating under support since 2012.

Confidential patient information requested

Confidential patient information including NHS number, name, date of birth, postcode and date of death were requested.

Background to Amendment

SSNAP have recently been commissioned to extend the work of the audit to include a work stream that would include the sharing of data between the SSNAP audit and NHS Ambulance Trusts. This would mean that SSNAP could analyse and report on aspects of pre-hospital care for the purpose of improving care by ambulance trusts and to report to NHS England.

Amendment Request

The amendment request set out the following two revisions to the existing support which was provided under the Regulations:

1. To extend the flow of data from SSNAP to NHS Ambulance Trusts in England in order to enable linkage of information held within the SSNAP audit database with pre-hospital care information held by Ambulance Trust. Data from the ambulance Trusts and SSNAP would be linked by ambulance job number and/or NHS number.

2. To extend the access to information recorded on the SSNAP database to enable all registered care providing teams the ability to view all data entered in relation to a patient across the care pathway, by removing the current viewing restrictions which limit view to retrospective care teams. This will enable any prior SSNAP team to view the care given to the patient up to and including the six month review on an individual patient basis.

Confidentiality Advisory Group advice

Public Interest

The CAG was assured that the proposed amendment had an established medical purpose, through the management of health and social care service. It was recognised as example that time to arrival at hospital was an important variable in the care pathway for patients who have suffered a stroke and there was a wider public interest in the inclusion of additional clinical information from the Ambulance Trusts on this basis. It was further commented that, by removing the viewing restrictions within the SSNAP audit database, any clinician who had been involved in the treatment of a particular patient would be able to review the complete care pathway across the six month period which would assist improvements in patient care and improve the understanding of care being delivered throughout the pathway. The Group was agreed that there was a clear public interest in the amendment proceeding and was content to provide a recommendation of support on this basis.

Support from Healthcare Quality Improvement Partnership (HQIP)

The letter of support for the amendment had been received as part of the submission from HQIP, controller for the audit programme. Ambulance Trusts had provided agreement in principle to the involvement with the audit, which would be managed by the applicant moving forward.

Data Flows

Whilst Members were supportive of the additional data flows between the audit programme and Ambulance Trusts in England, it was agreed that confirmation of the complete dataset to be included within the audit was required. This would ensure there was a comprehensive record of the wider clinical data items to be included in the audit database for reference.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that 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 2018.

It was confirmed within the amendment application that, if the request was supported, patient-facing notification materials and subsequent consenting materials would be updated to reflect the inclusion of data sharing between the audit and Ambulance Trusts in England and with previous care providers involved a patient's treatment pathways. It was agreed that sight of these revised materials was required.

It was noted that Trusts were able to make a monthly download of data from the SSNAP audit in relation to patients within their care. Members were unclear how any newly registered patient objections or declined consent would be applied to a dataset which had been downloaded by a participating Trust. The Group agreed that further information was required around the management of objection within downloaded extracts from the overarching audit dataset to ensure any dissent would be appropriately respected.

Confidentiality Advisory Group advice conclusion

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

Secretary of State for Health and Social Care, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information

1. Provide a definitive list of data items which would be shared with NHS Ambulance Trusts in England and supplementary clinical data which would be entered into the audit database.
2. Copies of patient-facing materials should be provided which have been updated in line with this amendment.
3. Provide further information the management of objection within downloaded extracts from the overarching audit dataset to confirm how any dissent would be appropriately respected.

Specific Conditions of Support (Provisional)

1. Support is extended to the data flows between the audit and NHS Ambulance Trusts in England.
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission - **Pending:**
   - **Net Solving Ltd shows a self-assessed score on V14.1, 2017/18 – confirmation is required of NHS Digital's reviewed grade, King's College London SSNAP has a published satisfactory reviewed grade on V14.1, 2017/18**.

4. AMENDMENTS – Research

a. ECC 1-05(b)/2012 (Sub Reference: 18/CAG/0155) – ALSPAC Study Young Adults: Enrolment and Consent for Record Linkage

i) Amendment: Extension to Include Parents and Carer (G0) Cohort

Background to the Amendment

The Avon Longitudinal Study of Parents and Children (ALSPAC) is a longitudinal birth cohort study consisting of approximately 14,000 patients across three generations of study participant families. The initial study was operated on a consented basis; however, an application was submitted to the CAG to follow-up enrolled patients via administrative datasets with support under the Regulations. This follow-up sub-study was entitled 'the PEARL Study'. Following a complex review process, the application received a recommendation of support in August 2012.

The study participants were recruited from an eligible population comprising any woman who was pregnant while living in and around the city of Bristol and due to deliver between 01/04/1991 and 31/12/1992. The study involved three generations:

- G0: the original pregnant women, the biological fathers and non-biological carers,
- G1: the original index children,
- G2: the children of the original index children.

The current recommendation of support relates only to the G1: Index Children. The recommendation of support extended to the follow-up of patients via various administrative datasets held by the then NHS Information Centre, a predecessor of NHS Digital.

The current recommendation of support extended to the processing of NHS number, date of birth and GP registration to facilitate the linkage process. Only pseudonymised data which included a unique reference number (ALPSAC ID) for each individual was available to the applicant.

Purpose of Amendment

The amendment submission set out three proposed changes to the application. This outcome letter relates only to the following request:

1.To extend the scope of support under the Regulations for the PEARL study to include the G0 sub-cohort of parents and carers of the original ALSPAC longitudinal study. The amendment sought support under the Regulations to follow-up this additional cohort via administrative datasets held by NHS Digital, on the same basis as was currently supported for the G1 index children cohort.

Confidentiality Advisory Group advice

The CAG acknowledged that whilst the original ALSPAC study had included the parents and carers of the index children as fully consented participants, the proposal which was currently supported under the Regulations was a sub-study of this original overarching research programme: the PEARL study. The title for the PEARL study was: '*Influences on psychosocial and physical health in early adulthood: phenotypic enrichment of the ALSPAC cohort through linkage to primary care electronic patient records and other databases: The Project to Enhance ALSPAC through Record Linkage (PEARL)*'. The PEARL study which is currently supported under the Regulations had to date focussed solely on the G1 cohort of original index children. Members stated that the amendment to extend this proposal to include the parents/carers of this index children cohort was a new request in terms of what had previously been considered by CAG.

The G0 cohort of pregnant women, biological fathers and non-biological carers were the original patient participants who were recruited to the ALSPAC study. This cohort had been recruited with the help of NHS staff during the course of care provided at antenatal scan clinics and within maternity wards.

The CAG recognised the value in the overarching ALSPAC programme, which would be further improved by increased data linkage undertaken in the PEARL study. It was however commented that from the documentation provided, the purpose of the extension to include the G1 parent/carer cohort within the PEARL protocol was not clear. This protocol was focussed on influences in health in early adulthood and it was unclear how this focus would transfer to the cohort of patients that were adults at the point of inclusion in the ALSPAC study in the early 1990s. Further information was required to understand the purpose of the proposed extension and how this could reasonably be presented as an extension to the existing PEARL protocol.

The Group agreed that to ensure there was a clear audit trail in relation to the G1 parent/carer cohort, a separate application would be required which focussed solely on this sub-cohort. Whilst the supplementary information provided by the applicants had been received, it was noted that the requested extension to include the G1 parent/carer sub-cohort was such a significant revision to the scope of the existing support, that the amendment documentation did not capture all information which was required to enable informed consideration by the CAG. It was further noted that provision of an application form in relation to the G1 parent/carer sub-cohort would also ensure there was a clear and complete record in relation to the scope of support which had been requested in relation to this group, in case of future queries.

Members agreed that assurance would be required as part of this submission that the Research Ethics Committee (REC) had provided a favourable ethical opinion to the amendment and copies of any review documentation should be provided to support the submission.

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:

1. A separate application should be completed within the IRAS system which relates specifically to the inclusion of the parent/carer (G0) sub-cohort of the original ALSPAC study within the PEARL study.

ii) Amendment: NHS Digital Linkage and Retention of Sensitive Information

Background to the Amendment

The Avon Longitudinal Study of Parents and Children (ALSPAC) is a longitudinal birth cohort consisting of approximately 14,000 patients across three generations of study participant families. The initial study was operated on a consented basis; however, an application was submitted to the CAG to follow-up enrolled patients via administrative datasets with support under the Regulations. This follow-up sub-study was entitled 'the PEARL Study' and received a recommendation of support in August 2012.

The current recommendation of support relates only to the G1: Index Children. The recommendation of support extended to the follow-up of patients via various administrative datasets held by the then NHS Information Centre, a predecessor of NHS Digital. The current recommendation of support extended to the processing of NHS number, date of birth and GP registration to facilitate the linkage process. Only pseudonymised data which included a unique reference number (ALPSAC ID) for each individual was available to the applicant.

The scope of support provided under the Regulations was scrutinised by NHS Digital as part of the review of a data sharing agreement. It was confirmed in correspondence dated February 2016 that NHS Digital did not believe the historic application and subsequent recommendation of support provided sufficient granular detail of the items of confidential patient information that would be processed or the data sets and items with which this would be linked. This historic correspondence was reaffirmed in August 2018 by a member of the Data Access Request Service (DARS) team. The outcome of the assessment was the determination by NHS Digital that a legal basis had not been established to support the data processing and linkage which was currently requested.

The initial recommendation of support which was given for the PEARL Study did not extend to the linkage with sensitive data fields, including sexual and mental health information. A condition was added to the recommendation of support that projects which requested this data would be required to submit an individual application supported by a favourable opinion from an NHS REC for review by the CAG. To date, five separate projects have been submitted and received a recommendation of support from the CAG as follows:

- CAG 7-06(a)/2013 – Accuracy of estimates for self-harm;
- 14/CAG/1032 – Association between IQ and self-harm;
- 15/CAG/0175 – Early life causes of depression and anxiety;
- 15/CAG/0176 – Predictors, prevalence and impact of chlamydia;
- 15/CAG/0177 – Substance use and mental health.

Purpose of Amendment

The amendment submission set out three proposed changes to the application. This outcome letter relates only to the following two requests:

1. To clarify the scope of the existing support which is in place under the Regulations, with regard to access to registry and personal demographic records held by NHS Digital. The request seeks to either confirm that the existing support extends to the linkage described or alternatively to request an extension to cover the items described in the amendment form. This included: birth register information, birth certificate information, marriage certificate information, death registration, cancer registration and detail from the NHS Personal Demographics Service.

2. To seek support to retain sensitive information which was collected under the five individually referenced applications, in order to repurpose this data for additional research purposes.

Confidentiality Advisory Group advice

Scope of Support – NHS Digital Linkage

The Group recognised that the initial application had described the proposed linkage with registry and personal demographics information held by the NHS Information Centre, a predecessor of NHS Digital, in broad terms as was the accepted practice at that time. The standards and specificity required within an application had understandably progressed in the intervening period since the initial consideration of this item. Members noted that the description which had been provided in the original application would not be considered to provide sufficient detail, by current standards, to describe the level of access to registry and personal demographics records which was requested. It was agreed, on this basis, that this request would be considered by the CAG as an amendment to the original scope of support which had been provided under the Regulations, and not a clarification around the scope of the existing support.

The CAG recognised that the ALSPAC cohort was a unique and rich dataset which was incredibly useful for research purposes, having been cited in over 2,000 academic papers. Members accepted that there was an extremely high public interest in the continuing work to improve the value of the ALSPAC cohort database through further follow-up under the PEARL study. The linkages described within the amendment application were very much in line with the spirit of the original recommendation of support.

The remit of the CAG is defined in section 251 of the NHS Act 2006 and its Regulations. Information that falls within the scope of Regulation 5 of the COPI Regulations is set out in the NHS Act 2006 and states it must firstly be 'patient information', which is defined at (s251(10)) and then 'confidential patient information' which is defined at s251(11). The Group noted that some of the data items cited within the amendment form clearly would not fall within the scope of these legal definitions and for these, support could not be provided. Marriage certificates were cited as an example from the dataset described which would not fall within the definition of confidential patient information.

The Group was content to provide a recommendation of support to the access and linkage with the registry data and personal demographics information held by NHS Digital which was cited within the amendment application form. Support was recommended on the basis that the remit of the CAG extended to information which fell within the definition of confidential patient information only. Members were clear that it would be the responsibility of the applicant, together with NHS Digital as the controller for the data sets, to determine which information fell within this definition and establish an alternative legal basis in relation to the processing and disclosure of information which fell outside of this definition.

Retention and Repurposing of Sensitive Information

The rationale provided to support the retention and onward repurposing of sensitive information which had been collated under the previous five application submissions, was that this would result in financial efficiencies on public and charitable funds, more timely delivery of research data to investigators and also increased data security as further disclosure and linkage would not be required. The Group was assured by the rationale, recognising that undertaking bespoke data linkages via NHS Digital was a costly and time-consuming process. By repurposing the data which had already been collected, this additional financial and time resource could also be repurposed and Members agreed that this was within the public interest. The Group also recognised that there was security issues associated with repeat data linkages which would also be avoided through the retention of the existing data.

Reviewing the conditions of support which had been attached to the five referenced applications, the Group noted that a specific condition had been attached to the application references CAG 7-06(a)/2013 and 14/CAG/1032 which stipulated that the supplementary sensitive information which had been collated for the purposes of these individual studies would only be retained for the duration of the specific project only, and not the duration of the overarching ALSPAC programme. Members agreed that further clarification was required around the status of the two referenced applications as it was recognised that both projects were

overdue submission of an annual review. As such, it was unclear whether these projects were still live, or if the sensitive data which had been collated for the purposes of the proposals had already been destroyed in line with the conditions of support, if the projects were complete.

The Group was in agreement that support could be recommended for the retention of the sensitive data fields in order that this information could be repurposed for wider research aims. It was noted that as support under the Regulations was currently only provided to the linkage and retention of data in relation to the index children within the ALSPAC cohort, data within these wider proposals could only be retained for this sub-cohort. Members affirmed the existing condition of support and agreed that submission of individual applications to seek support under the Regulations for the use of this sensitive information for proposed wider research purposes remained a requirement.

Confidentiality Advisory Group advice conclusion

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

Request for Further Information

1. Confirm the status of the two linked applications: CAG 7-06(a)/2013 and 14/CAG/1032 and clarify whether the sensitive data items collated under these two references would be retained for ongoing research purposes.
2. Confirmation of the REC's favourable ethical opinion for the amendment.

Specific Conditions of Support (Provisional)

1. Support relates to the index children (G1) of the original ALSPAC cohort only.
2. Support extends to the linkage and access to confidential patient information held within the registry datasets and personal demographics information cited in the amendment application. Support does not extend to those items/data sources that are not clearly confidential patient information. It is the responsibility of the applicant, together with NHS Digital, to determine which of the specific data items requested would fall within the legal definition set out in the NHS Act 2006. An alternative legal basis would need to be established for information which does not fall within the legal definition set out in the NHS Act 2006.
3. Support is extended to the retention of sensitive information collated under the wider application references (exact references to be confirmed) to enable this information to be repurposed for wider research aims. Individual applications should be submitted to seek support under the Regulations for the use of this data for a wider research purpose.
4. Favourable opinion from a Research Ethics Committee (**Pending**).
5. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital and ALSPAC have a published satisfactory reviewed grade on V14.1, 2017/18**).

b. 18/CAG/0054 – The SUMMIT Study

Background

This application from University College London set out the purpose of medical research to investigate the feasibility of introducing low dose computed tomography (LDCT) screening to a group of adults at high risk of lung cancer. The purpose of the application to the CAG was to seek support under the Regulations to allow the research team access to GP record systems to enable potentially eligible patients to be identified and invited to participate in the study.

This application was initially considered under reference 17/CAG/0194 at the CAG meeting held on 24 November 2017, where recommendation was deferred pending further information from the applicant. The revised submission under reference 18/CAG/0054 was considered at the CAG meeting held on 05 April 2018, where a provisionally supported outcome was issued. A final fully supported recommendation was issued on 05 June 2018.

Purpose of Amendment

The amendment submitted sought approval for a number of significant changes to the project, as summarised below:

- Inclusion of an additional new patient cohort in the study – this will comprise of aged-matched individuals not at high-risk of lung cancer (Group B). It is proposed that 25,000 patients will be recruited to this group. Recruitment of patients in this group will follow the same pathway as the main patient group – potentially eligible patients will be identified from GP records and invited to participate in the study.
- The study title would also be amended to reflect this change from 'Lung cancer screening study using low dose CT to support the development of blood tests for early cancer detection' to 'Cancer screening study with or without low dose lung CT to validate a multi-cancer early detection test'.
- The age range for eligibility has been amended from 55-80 years to 50-77 years.
- Support was originally recommended to allow access to 100,000 patient records in order to recruit the 25,000 patients at high-risk of lung cancer. The amendment requested that this was extended to 800,000 patient records to ensure the 50,000 recruitment target (25k per cohort) could be achieved.
- Support was requested to extend the duration which information on patients who do not respond to the formal consent request (non-responders) in retained from 15 months to 10 years for analysis purposes.

Confidentiality Advisory Group advice

Amendment Review Pathway

The amendment submission was initially received in June 2018 and shared with a Sub-Committee of the CAG which had been involved in the initial application review in order to establish the most appropriate review pathway. The Sub-Committee agreed that, as the proposed amendments were so significant, the amendment application required consideration at a full CAG meeting.

Public Interest

The CAG was assured that there was an ongoing medical purpose in the proposed activity, which was medical research.

The amendment had been submitted for review by the Research Ethics Committee, which had accepted the revisions as a substantial amendment and provided a favourable ethical opinion to the request. Members agreed that the confirmation of the REC opinion for the amendment further strengthened the public interest in the proposed changes described.

Members considered the proposed inclusion of the second cohort of age-matched patients who were not at high-risk of lung cancer. Members recognised that the blood test being trialled within the study had shown early promise in the early detection of cancer. As a lower risk patient group, the applicant had explained that it was envisaged that recruitment of patients within this cohort would be more difficult as there was no potential health benefits from participation in the study. The CAG was assured by the rationale provided and accepted the extension to the potential recruitment sample, to enable access of up to 800,000 patient records in order to achieve the recruitment target of 50,000 patients across the two cohorts, was necessary. Recruitment would continue to be carried out on a rolling basis so once the target recruitment had been achieved, no further patient records would be accessed. The CAG was assured that there was a wider public interest in exploring the efficacy of the blood test further with the newly described patient group.

The Group had reservations about the proposed extension to the retention period of confidential patient information in relation to patients who did not respond to the formal invitation to participate in the study. The amendment set out a request to retain this information for the duration of the study, to enable longer term follow-up over 10 years. Members were unclear of the purpose for this ongoing retention and the intended outcomes as the documentation did not clearly describe what the proposed future follow-up and linkages were. It was agreed that the public interest in this element of the amendment had not been clearly articulated. The CAG agreed that further information was required in relation to the long term follow-up and necessity for complete case ascertainment within this from those invited to participate in the study, including non-responders, in order to establish a public interest in this element of the proposed amendment. It was commented that further issues had been identified with this element of the proposed amendment, which were considered in turn below.

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 proposal was a participant identification study, whereby confidential patient information would be accessed with support under the Regulations in order to identify the cohort of patients to be invited to participate in the trial. The CAG was assured that seeking consent from all potential patients in advance of the formal invitation process was not feasible due to the cohort size.

- Use of anonymised/pseudonymised data

Members recognised that access was required to confidential patient information in order to facilitate the invitation process.

- Long-term Follow-up – NHS Digital

The Group queried whether there was scope for the long-term follow-up of health outcomes to be facilitated by NHS Digital in order to limit the ongoing access to confidential patient information by the research team. Members recognised that support under the Regulations would be still be required to legitimise the information retention and processing undertaken by NHS Digital; however, the proposal would limit the applicant's ongoing access to confidential patient information without consent. The CAG agreed that consideration should be given to this suggested way forward and a response provided to confirm agreement to this, or if the proposed is not deemed to be feasible, a strong rationale would be required to support this decision.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient. Members were satisfied that recruitment of the new Group B cohort would be undertaken on this same basis as the original high-risk Group A cohort, using the items of confidential patient information that were currently supported. The Group remained content that the items of confidential patient information requested were appropriate and proportionate to facilitate the recruitment process.

The amendment application did not clearly articulate which items of confidential patient information would be retained to facilitate the proposed long-term health outcomes follow-up of all patients invited to participate in the study. The items of confidential patient information required to facilitate the recruitment process were extensive and the CAG commented that it would be expected that those identifiers required to facilitate the long-term follow-up would be lesser. Members agreed that confirmation was required from the applicant in this area.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The amendment submission did not describe any wider patient and public involvement and engagement activity in order to test the acceptability of using confidential patient information from the low risk-patient cohort without consent. Members stated that as the amendment proposed a significant extension to the study, beyond what was initially proposed, further activity was required in this area in order to seek the views of a relevant patient and public audience about the proposed changes. Feedback from this activity would be required – if the responses given were negative, the CAG would take this into account when considering whether support can be recommended for the extended study scope or whether further actions were necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Members recognised that the established notification mechanism which was in place for the study would be extended further to account for additional patient cohort. It was noted that patients who were eligible to participate in the lower risk Group B cohort, may be less likely to visit their GP practice, as they were less likely to have health issues. The Group acknowledged that the notification mechanism had been supported in relation to the original high-risk cohort and was not mandating further extension; however, it was queried whether there was potential for any wider publicity for the study, recognising the significant change in scale and scope. The applicant would be asked to consider ways in which the communications strategy supporting the study could be widened and provide response.

The Group considered the revised patient-facing materials which had been provided to support the amendment application. It was recognised that the documentation had already been considered and provided with a favourable ethical opinion by the REC; however, some inconsistencies were identified across the documents, particularly in relation to the retention period for confidential patient information, which would need to be rectified to ensure accuracy across all documents provided.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with data protection legislation, which is now the General Data Protection Regulation (GDPR) and Data Protection Act (DPA) 2018. Members were unclear how the proposed ongoing retention and processing of confidential patient information in relation to patients who had been formally approached to consent to participate in the study, but did not respond to this request, was compliant with the requirements of the GDPR. It was further commented that as the patients were classified as non-responders, it was also unclear how the proposed ongoing processing of confidential patient information in relation to this group was in line with the established guidance of the Information Commissioner's Office (ICO) around managing non-responders.

The CAG agreed that further information was required from the applicant in confirm how the ongoing retention and processing of confidential patient information in relation to non-responders for a further 10 year period was compliant with the requirements of the GDPR and the ICO guidance around managing non-response. Satisfactory assurance would need to be provided in this area before the CAG could fully consider whether support under the Regulations, to prevent a breach of the common law duty of confidentiality, could be recommended for this specific element of the amendment request.

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.

Request for further information (Summary)

1. Provide further information around the proposed long-term follow-up, including an overview of the proposed data linkage which would be carried out and the intended outcomes of this follow-up, in order to establish a public interest in this activity proceeding.
2. Consider whether the long-term follow-up can be facilitated by a third-party organisation, NHS Digital as example, in order to limit the ongoing access to confidential patient information without consent by the research team. If this is not deemed to be feasible, a strong rationale would need to be provided to support this decision.
3. Confirm what items of confidential patient information will be retained in facilitate the long-term follow-up, providing a justification for each data item required.
4. Provide further information to explain how the proposed ongoing retention and processing of confidential patient information in relation to non-responding patients is compliant with the General Data Protection Regulation and the Information Commissioner's Office guidance around managing non-response. Satisfactory assurance of compliance here is required prior to further consideration of the provision of support under the Regulations to prevent a breach of the common law duty of confidentiality.
5. Further patient and public involvement and engagement activity should be undertaken to test the acceptability of the proposed study extension and provide an overview of the feedback received. If the responses given are negative, the CAG would take this into account when considering whether support can be recommended for the activity, no whether further action is required.
6. Consideration should be given to ways in which the communications strategy for the project can be extended, to promote the study in a wider public arena which is more accessible to the additional patient cohort. Provide an overview of any additional communications strategies which will be employed, together with any documentation required to facilitate this, for consideration by the CAG.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 30 July 2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – by email from NHS Digital dated 05 June 2018 in respect of Version 14.1, 2017/18 for the following:**
   - CFH Docmail Ltd,
   - University College London,
   - University College London Hospital NHS Foundation Trust,
   - Amazon Web Services,
   - Participating GP practices (600 practices) - Not requested for each site; support is based on the assumption that the applicant will ensure that satisfactory security assurances are in place for each site.

5. NEW APPLICATIONS – Research

a. 18/CAG/0133 – QUEST Follow-up Study Wave 3

Purpose of application

This application from Kings College London set out the purpose of medical research which aimed to assess the epidemiology of ASD Autism Spectrum Disorder (ASD), which is a severe and lifelong

developmental disability affecting about 1% of children and characterized by pervasive impairments in social communication, and also stereotyped and restricted interests.

The reason for the application was that at QUEST 2, the applicant failed to make contact with 18 patients who had participated in the original QUEST study. The current submission is seeking support under the Regulations to attempt to retrace these 18 patients and invite them to participate in QUEST 3.

A recommendation for class 2, 3, 4 and 6 support was requested to cover this specific element.

Confidential patient information requested

Cohort

18 patients who had previously consented to participate in the QUEST study at wave one, with whom contact failed following tracing at wave 2 of the follow-up.

The following items of confidential patient information are requested for the purposes of sample validation and to facilitate the invitation process:

- Name,
- NHS Number,
- Date of Birth,
- Date of death,
- Complete address,
- Postcode,
- Sex.

Confidentiality Advisory Group advice

Background to the Submission

For background purposes, QUEST 2, a second wave follow-up, was carried out in 2015 in order to follow-up the children at ages 10-14 years. An application was made to the CAG at this time under reference 15/CAG/0126, in order to seek up to date contact information for families involved in the original study who were now lost to follow-up so as to invite them to participate in the next wave of the study. Support had been recommended for that application.

The current application related to the follow-up of participants who were involved in the original QUEST study, which was operated on a fully consented basis. In this third "wave" of the QUEST study (time 3), the applicants wish to follow up the children again now that they are aged 12-16 years old to determine which young people have persistent severe maladaptive behaviour or mental health problems, and to determine which factors were predictive.

An initial application for QUEST Wave 3 was received in July 2017 under reference 17/CAG/0102. The applicants were seeking to make contact with families who participated in QUEST 1, who had been traced for QUEST 2 with support under the Regulations via application 15/CAG/0126. However, contact at the second wave of the QUEST project had led to the issue that no response had been received from 18 patients, and as the study was replying upon explicit consent to legitimise the data processing at that time, non-response could not be considered to meet the necessary threshold of valid consent under the Data Protection Act 1998 (as was current at that time) to continue processing the cohort information.

Following receipt of the application in 2017, the application was assessed according to standard procedures with the outcome being that this initial application was withdrawn by the applicant. Following advice from the Confidentiality Advice Team, this included the element that the application did not clearly reflect the proposed activity which the CAG was being asked to consider. After withdrawal of the application, further communication took place with the applicant but no formal advice was provided by the CAG at that time. This communication highlighted that it is a statutory requirement for any support provided

to be consistent with the principles of the Data Protection Act. It was clarified that as the participants had been formally been asked to consent to participate at QUEST 2 and had not responded, that consent was not in place as a condition for processing under the DPA 1998. It therefore appeared that the application was seeking to change the condition for processing under the DPA, which the CAG understood not to be a legitimate approach based upon previous ICO guidance to the CAG regarding non-response. The CAG was supportive in principle of the activity proceeding, but required the application to evidence that the activity was not unintentionally in breach of data protection legislation at that time.

Further conversation took place with the applicant in 2018 where it was flagged that the implementation of the GDPR had a two-year window for data controllers to assess the condition for processing, and to review, strengthen, or amend the condition for processing in light of GDPR. The applicant was advised to contact the ICO to seek advice in light of the current guidance on '*Managing Non-Response'* and return to CAG with the appropriate evidence of data protection compliance.

Subsequent correspondence was received from the applicant in April 2018 clarifying the intention to change the lawful basis for the retention of confidential patient information from QUEST 1, in light to the upcoming GDPR, from explicit consent to another lawful basis. The applicant was advised that a refreshed application should be provided to the CAG in relation to the tracing at QUEST 3 for the 18 participants with whom contact had failed in relation to the QUEST 2 follow-up.

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members recognised the value of the longitudinal follow-up of the established patient cohort and the extent of the work undertaken by the applicant to remain engaged with this patient group was commended. It was recognised that of the complete patient cohort of 277 patients, current evidence suggested that only around 20 of these patients would be expected to go on to develop severe maladaptive behaviours (SMB), which were described as problems so severe that they would jeopardise all aspects of everyday life for the patient, from living with their families, attending local schools and participating in community activities. The applicant explained that relatively little was currently known about the factors that predict which children with Autism Spectrum Disorder (ASD) would go on to develop SMB. Members were assured that there was a strong public interest in the proposed wave three follow-up on this basis.

The CAG was supportive of the application intentions and recognised the value and public benefit in the third wave follow-up of this project proceeding with as complete a patient sample as possible. However, while being supportive in principle, Members agreed that there were outstanding points around whether the proposal was compliant with current data protection legislation in light of pre-existing guidance and a potential practicable alternative had been identified which would need to be addressed before a final recommendation of support for the application could be made.

ICO Guidance on Managing Non-Response

Prior to the implementation of the GDPR, the applicant had been directed to the guidance on managing non-response under DPA legislation, its impact on seeking support, and what would be required to address evidence of compliance. In short, the guidance indicated that at the time, relying upon explicit consent as a condition of processing under the DPA meant that a data controller could not change its condition for processing in the event of non-response. If this situation was in place, an application could not be made to the CAG.

Following advice and advent of GDPR, the applicants had changed the lawful basis for the continued retention and processing of personal data provided by participants at QUEST 1, from explicit consent to an activity which is necessary for the performance of a public task. Confirmation of assurance of this approach had not been provided by the ICO, noting that the CAG is not constituted to provide an authoritative determination of GDPR/DPA compliance.

The Group reiterated that it was very supportive of the project and sympathetic to the issues the applicant had encountered in establishing further follow-up of the initial participants; however, as set out at section

251(7) of the NHS Act 2006, a recommendation for support under the Regulations cannot be provided to an activity which may be inconsistent with current data protection legislation. On this basis, assurance would be required from the ICO around whether, due to the change in lawful basis for data processing, the guidance around managing non-response would still apply, or would not prevent the CAG recommending support.

The CAG agreed that the applicant would be required to seek guidance from the ICO on this point and provide confirmation of the outcome. If the ICO was supportive of the application proceeding and confirmed that the proposed activity was not inconsistent with the current and previous guidance, Members confirmed they would be content to receive a resubmission of the application supported by this decision from the ICO. Copies of the correspondence with the ICO and the formal outcome would be required to support any further 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 Group recognised that the purpose of the application was to update contact information for the previous participants to facilitate an approach for consent to participate in the third wave of the QUEST study. It was accepted that it was not feasible for the research team to seek prior consent for this contact.

- Use of anonymised/pseudonymised data

It was recognised that confidential patient information was required to facilitate the contact with patients, which could not be otherwise achieved.

- Approach by the Direct Care Team

It had been queried whether the initial approach about the QUEST 3 follow-up could be made by the patient's current treating care team. If this was the case, this would mean that an application to the CAG would not be necessary as there would be no breach of confidentiality. The CAG considered this point as it was agreed that making an approach to patients via their direct care team appeared to provide a practicable alternative to seeking support under the Regulations to trace these patients. It was further commented that, by allowing the direct care team to make the initial approach about the study, this would allow any families who had actively chosen not to respond to the QUEST 2 contact to reaffirm this dissent and prevent any further unwanted contact from the research team.

The applicant had previously explained in response to this query that clinical care teams had been consulted at an earlier phase in the recruitment but had only been able to assist in relation to those families which still lived within the district (i.e. Bromley and Lewisham). The applicants stated that as further time had lapsed since this previous contact, they anticipated that a greater number of families would have moved out of the area and could not be followed up by the direct care team.

Members commented that the relevant patient cohort would have severe learning difficulties and the community of clinicians in this field is considered to be small, therefore if the patient had moved out of the area the relevant clinicians are likely to be heavily involved in the case. As the application concerned only 18 patients, Members agreed that making contact with the last known direct care team in order to confirm whether the family had relocated out of the area was not likely to be an onerous task. It was suggested that, potentially, families that were caring for children with complex needs seemed less likely to relocate due to the reliance on the specialist services required to support patient care. It was also likely that this patient population would to be in closer contact with care providers. For those patients still residing in the district, a request could be made by their direct care team to confirm whether the family was interested in

participating in the third wave follow-up and seek permission for updated contact information to be shared with the research team.

The CAG noted that this option appeared to provide a balance between the applicant requirements to follow-up all previous participants, but also facilitated a means for families to affirm any previous dissent and prevent further contact from the research team. The applicant's would be required to explore this option as a practicable alternative prior to submitting a further application to the CAG. If it was determined that this proposal was not feasible, the revised application would need to provide evidence to support this.

Protocol for Tracing Patients

The Group commented the protocol for tracing patients remained unclear. It was stated that the study newsletter would initially be sent to the families, following receipt of updated contact information. Members agreed that the most recent newsletter document, sent in January 2018, was a useful tool for keeping those families who were engaged with the study updated on the ongoing activities; however, it did not appropriately address families with whom contact had failed at the second wave follow-up. It was suggested that for the 18 families which the applicant was intending to trace for involvement at the third wave follow-up, the newsletter should be supported with a covering letter which explained their situation and how this further follow-up had come about. It should also provide clear information around how the families could raise an objection to further follow-up, prior to the research team attempting contact by telephone to facilitate a dissenting mechanism for those families who no longer wished to be involved with the QUEST project. It was agreed that, should a further application be made to the CAG, revised documentation would be required to support the tracing protocol.

QUEST 3 Patient Information Materials and Consent

Members considered the information sheets and consent forms which had been provided to support the third wave follow-up at QUEST 3. It was noted that the documentation did not ask participants to provide consent to future tracing of updated contact information for further follow-up, should their contact details no longer be valid. The Group recommended that the applicants revise the information sheet and consent form to ensure that this eventuality was covered as part of the formal consenting process for involvement at QUEST 3, to future-proof the project and prevent the requirement for any further applications to trace patients.

Recommendation

The CAG raised the following point for consideration only by the applicant – it did not form part of the formal advisory recommendation:

1. It is recommended that patient information and consent materials for the QUEST 3 follow-up are updated to seek confirmation from participants that they can be traced via the NHS Personal Demographics Service for future follow-up, in case the contact information held by the research team is no longer valid.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed, while supportive in principle of recommending support, requested assurance that there was no other practicable alternative, and evidence that the approach would not be inconsistent with data protection legislation. Further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Further information required

The following points would need to be addressed by the applicant, prior to submitting a further application to the CAG.

Practicable Alternatives

1. The applicant should explore the possibility of follow-up via the patients direct care team as a practicable alternative for seeking support under the Regulations to trace patients via the NHS Personal Demographics Service. Contact should be made with the last known care provider, in order to confirm whether the patient still resides within the region and to facilitate initial contact about the study by current care providers. *If following this approach, support would not be required.* If this proposal is *evidenced not to be* feasible, a revised application could be submitted to the CAG to seek support under the Regulations for this activity. The revised application should evidence how tracing via the patient's last known care provider was not a feasible alternative.

Assurance from the Information Commissioner's Office

2. The applicant is asked to seek guidance from the ICO in relation to the application to confirm whether, following the change to the lawful basis of data processing, the ICO's guidance around managing non-response would no longer apply to these patients. If confirmation is received that the guidance would not apply in these circumstances, a revised application could be made to the CAG, supported by this formal outcome. If submitting to CAG, this assurance must be evidenced in writing by a representative of the ICO and it advised that this letter is provided to the ICO so they have an awareness of the factual background and context.

Tracing Protocol – Supplementary Documentation

3. Should a revised application be put forward to the CAG, supplementary documentation is required to support the tracing activity: a covering letter should be drafted, which will be circulated with the newsletter to those families who will be traced with support under the Regulations. This should provide specific information to this sub-cohort of patients, which explains how they have been traced following non-response at QUEST 2 and provide a clear mechanism to raise an objection to further contact from the research team.

b. 18/CAG/0141 – Bone Imaging Statistical Learning

Purpose of application

This application from Imperial College London set out the purpose of medical research which aims to develop automated data-driven software to assist with diagnosis of disorders in joint extremities. This will be used to develop a learning tool for junior doctors and an assisting tool for pre-surgical planning.

A selection of 2,200 scans (CT, X-Ray or MRI scans) would be selected for inclusion in the study from patients who were referred by either their GP or consultant to Imperial NHS Trust with lower limb extremity issues. The CAG is being asked to provide a recommendation of support to enable the research team to access NHS PACS database (Primary and Acute Care Systems) in order to identify the scans to be included in the study and export these scans and associated data from the radiology report in an anonymised format for analysis.

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

Confidential patient information requested

Cohort

All patients aged 18 and over who underwent a standard departmental x-ray, CT or MRI scan at Imperial NHS Trust for medical issues regarding bones or joints in upper or lower extremities. 2,200 scans will be included in the study, from 2013 to present.

Access is required to full patient record within the NHS PACS database to enable extraction of an anonymised scan and associated clinical information. No confidential patient information will be extracted for analysis.

Confidentiality Advisory Group advice

Public Interest

The CAG was assured that the project described an appropriate medical purpose which was medical research. Members were unclear what the outputs would be for the project. The application stated that an automated data-driven software programme would be developed which would assist with the diagnosis of disorders in joint extremities to be used as a learning tool for junior doctors and a tool for pre-surgical planning; however, it was unclear from the information provided how this would be achieved. The Group agreed that further clarification was required around the intended outputs to confirm the public interest in the project proceeding.

Practicable alternatives

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

- Feasibility of consent

The Group recognised that this was an academic project with limited funding and resources. It was acknowledged that, to operate the project on a consented basis would involve wider processing of confidential patient information and Members were assured in this instance that this was not a feasible alternative.

- Use of anonymised/pseudonymised data

The CAG noted that whilst confidential patient information would be visible within the PACS database, this was not required for analysis.

- Extraction by the Direct Care Team

Due to the volume of scans required for the project, the applicant advised that it was not feasible for data extraction to be undertaken by the direct care team. Members were assured by the rationale provided as the data extraction process would be onerous for busy clinicians.

Cohort

The applicant had specified that the patient cohort would be sampled from scan records within the PACS system from 2013 to the present. Members agreed that further clarification was required to provide a specific time period for the inclusion of patients, detailing an open and close date for the sample.

Justification of identifiers

The Group recognised that confidential patient information was not required for the study analysis; however, the applicant would have access to the complete patient record within the PACS system in order to extract the pseudonymised data.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. It was recognised that support under the Regulations was required to facilitate the data extraction process, as only

pseudonymised scans and associated data would be extracted for analysis. The anticipated duration of the data extraction process was unclear from the application and Members agreed that confirmation was required to understand the duration which confidential patient information would be accessed.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The project was considered by seven members of a muscular-skeletal patient and public involvement group via email. Whilst the feedback provided was supportive of the project, Members commented that the activity in this area was limited and further work should be undertaken as the project progressed, potentially with relevant associated charities. An overview of planned activity in this area would be required prior a final recommendation of support coming into effect. Feedback from the activity undertaken would be required at the time of first annual review. If the responses given were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that 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 2018.

The applicant explained that information relating to the study would be displayed on the MSK-Lab Clinical Trial homepage and provided a copy of the text for review. Members commented that the text did not provide a clear overview of what data would be accessed, to enable a patient to identify themselves within the cohort or provide details of how a dissent could be raised. It was also unclear whether patient records would be checked for evidence of historic dissent.

The Group agreed that further work was required in this area. It was suggested that information about the study could also be displayed within the dedicated research area of the Imperial College Healthcare NHS Trust website, as this was more accessible to patients. It was agreed that the text should be revised to provide a clearer overview of the study, the patient cohort to be included and a mechanism for a patient to raise an objection. An overview of the dissenting mechanism would be required for information, together with confirmation of any lead-in time if appropriate.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. Confirmation of a favourable ethical opinion was required prior to any final recommendation of support coming into effect.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the General Data Protection Regulation (GDPR) and Data Protection Act (DPA) 2018. Further information is required from the applicant to confirm what lawful basis was being relied upon for the processing of data and special category data in order to show compliance against principle A of the GDPR.

Outstanding Documentation

A letter of support for the project from the Caldicott Guardian (or organisational equivalent) of the applying organisation is a mandatory document to support the CAG application. This document had not been provided in the initial application submission and remained outstanding.

Confidentiality Advisory Group advice conclusion

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

Request for further information (Summary)

1. Provide further information around the intended outcomes of the project to establish a public interest in the activity proceeding. Further clarification should be provided around how the extracted scans and clinical information would be used to create an automated diagnosis software tool and how this would facilitate junior doctor training and pre-surgical planning.
2. Provide a specific timeframe for patient inclusion in the study, i.e. DD/MM/YYYY to DD/MM/YYYY.
3. Confirm the expected duration of the data extraction process; in order clarify the anticipated duration of support required under the Regulations.
4. Further patient and public involvement and engagement activity should be planned to be undertaken as the study progresses – provide an overview of planned activity to be carried out.
5. Patient notifications and dissent – further work is required in this area to address the following points:
    a. The draft website text should be revised to provide a clearer overview of the study, what information would be accessed and extracted for analysis, the patient cohort to be included and also provide details of how a patient can raise an objection to the use of their data for these purposes,
    b. Explore whether this information can also be displayed in the research area of the Imperial College Healthcare NHS Trust website,
    c. Provide details of how a project-specific objection mechanism would be operated for the study,
    d. Confirm whether patient records would be checked for any evidence of historic dissent for the use of information for research purposes and confirm this would be respected.
6. Confirm what lawful basis is being relied upon for the processing of data and special category data in order to show compliance against principle A of the GDPR. Further information can be found on the HRA website at the following link: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/
7. Provide a letter of support from the Caldicott Guardian (or organisational equivalent) from the applying organisation in support of the project.

Specific conditions of support (Provisional)

1. Feedback from ongoing patient and public involvement and engagement activity is required at the time of first annual review. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary
2. Favourable opinion from a Research Ethics Committee (**Pending**).
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Imperial College Healthcare NHS Trust has a published satisfactory reviewed grade on V14.1, 2017/18**).

c. 18/CAG/0142 – A Population Based Study of Genetic Predisposition and Gene-Environment Interactions in Breast, Ovarian & Endometrial Cancer

Purpose of application

This application from the University of Cambridge sets out the purpose of medical research which is part of the overarching SEARCH programme, which is a study which is investigating the role of inherited genetic variation in cancer risk and clinical outcomes. The focus of this study is breast, ovarian and endometrial cancers. Potentially eligible patients will be identified and invited to participate in the study which will require provision of a tumour sample and completion of questionnaires. The primary research question is to investigate the role of germline genetic variation in susceptibility to breast, endometrial and ovarian cancer; predisposing to different molecular subtypes of breast, endometrial and ovarian cancer; and their determining of clinical outcomes.

The SEARCH study started recruiting breast cancer cases from the region served by the former East Anglian Cancer Registry in 1996. The study was expanded to include ovarian cancer in 1999 and endometrial cancer in 2001. In the following 20 years the study has recruited over 15,000 patients into the breast cancer study and over 3,500 patients into each of the endometrial and ovarian cancer studies. It is stated that larger genome-wide association studies (GWAS) are required to provide evidence and identify additional common risks across cancers, which is the justification provided to support the ongoing recruitment into the studies. Historically, the study has recruited via the cancer networks; however, the proposed application proposed a change in methodology to facilitate recruitment via the NCRAS database.

The purpose of the application to the CAG is to seek support under the Regulations to support the identification of eligible participants and recruitment process. There are two proposed recruitment pathways for the study, only one of which requires CAG consideration. These are as follows:

- Public Health England will identify potentially eligible patients from the NCRAS database (National Cancer Registration and Analysis Service). This list of eligible patients would be disclosed to NHS Digital to enable list cleaning to undertaken and updated contact details for the patient and their GP to be added to the sample, prior to its release to the research team. This process will be undertaken on an annual basis and support is requested on an ongoing basis to facilitate this recruitment method. This recruitment pathway requires to the establishment of a legal basis under the common law duty of confidentiality to legitimise processing.
- Local cancer networks identify eligible patients and invite them to take part in the study by providing the study information leaflet.

A recommendation for class 3 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

Eligible participants are men and women diagnosed with breast cancer and women diagnosed with endometrial or epithelial ovarian cancer in England, Wales and Scotland. Patients must be aged between 18 and 69 at diagnosis, and have been diagnosed during the last five years. Patients will be excluded from the recruitment exercise if: they have registered an objection to their data being used beyond their individual care, they do not have a current GP practice registration or their GP indicates that the patient is unfit to be contacted for any reason, e.g. those who are seriously ill or cannot provide informed consent.

The following items of confidential patient information are required to facilitate the recruitment of patients and will be provided by Public Health England's NCRAS database and detail cleaned by NHS Digital prior to recruitment:

- Name,

- NHS Number,
- GP Registration and address details,
- Date of birth,
- Full Address and Postcode.

Confidentiality Advisory Group advice

Public Interest

The CAG was assured that the project defined an appropriate medical purpose which was medical research. It was recognised that this was a longitudinal project which had been established in the 1990s, with recruitment previously managed via the local cancer networks. This application described a change in methodology which would identify eligible patients centrally via the National Cancer Registration and Analysis Service (NCRAS) at Public Health England, which required a recommendation of support under Regulations to legitimise the data processing. Members agreed that there was a clear public interest in the project continuing as gaining a better understanding of inherited genetic variation in cancer risk and the associated clinical outcomes would improve patient care in the future. The Group was assured that the public interest in the ongoing project justified processing of confidential patient information without consent.

Practicable alternatives

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

- Feasibility of consent

It was recognised that support under the Regulations was being sought to facilitate the study recruitment processes, in order to invite patients to provide consent to their participation. Members accepted that it was not feasible to seek prior consent from patients.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the recruitment process which could not be achieved with a less identifiable data set.

- Invitation Distribution by Public Health England

The applicant confirmed that Public Health England (PHE) did not have capacity or the resource to distribute the research invitation materials on behalf of the study team, as the local networks had previously undertaken. Members accepted the rationale as it was recognised that the recruitment process was quite onerous and was not within the remit of the NCRAS team to facilitate this on behalf of the research team.

Justification of identifiers

The CAG was assured that the items of confidential patient information requested were appropriate and proportionate to facilitate the proposed recruitment activity. No issues were raised in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Support was requested on an ongoing basis in order to facilitate continual recruitment to the study; however, the exit strategy from support under the Regulations for individual patients would be consent.

The applicant had stated an intention to retain NHS Numbers for patients who do not respond to the project invitation request or decline participation for five years to ensure that these are individuals were not

approached again about the study. Members were unclear how this proposed retention was compliant with current data protection compliance or in line with the Information Commissioner's Office (ICO) guidance around managing non-response. It was also commented that it was unclear how credible the risk was of re-approaching a patient as it was assumed that NCRAS would not repeatedly provide confidential patient information in relation to the same patients. The Group agreed that this ongoing retention did not appear to be justified and the applicant would be asked to reduce this duration to a more acceptable timeframe. If the applicant deemed this ongoing retention necessary, a stronger rationale would need to be provided to support this, together with a clear explanation of how this ongoing retention was compliant with current data protection legislation and the ICO guidance around managing non-response.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. It was noted that activity had been undertaken in this area across the history of the project; however, there had been no interaction specifically focussing on the proposed change to the recruitment methodology. The Group commented that as the revised recruitment process involved processing confidential patient information without consent, views of an appropriate patient and public group should be sought in order to test the acceptability of this process. The applicant had explained wider engagement activity had been undertaken directly by Public Health England, for which the outcomes remained pending. Members agreed that feedback from this activity would also be required. If the responses given were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that 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 2018. The applicant had provided copies of the patient information materials which would be used to support the invitation process and explained that these documents would also be supplemented by a copy of the NCRAS patient information leaflet. Members also reviewed the information which was available on the overarching SEARCH research programme website. The Group noted that neither the information materials, nor the details available on the website, made it clear how a patient could raise an objection to the use of their information for the purposes of the research programme. It was recognised that there was a link to the NCRAS website from the study site, with a further link to how patients can opt-out of the cancer registration service; however, this did not account for patients who only had an objection to the use of their information for the purposes of this particular study.

The CAG agreed that project-specific communication would be required which explained how a patient could dissent to the study alone. The information should also provide a clear overview of the recruitment process and how data would be shared between the research team, Public Health England, NHS Digital and patient's GPs. It was commented that the patient-facing recruitment materials should also be updated to provide an overview of the recruitment process and clear information around how a patient can raise an objection or decline consent to their involvement in the study. It was recommended that these materials were reviewed as part of the wider patient and public engagement activity to ensure that the revise documents are considered acceptable to a public audience.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. The applicant explained that a substantial amendment had been submitted to the REC in relation to the change of recruitment methodology – confirmation was required that this amendment had received a favourable ethical opinion prior to any final recommendation of support coming into effect.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the General Data Protection Regulation (GDPR) and Data Protection Act (DPA) 2018. Further information is required from the applicant to confirm what lawful basis was being relied upon for the processing of data and special category data in order to show compliance against principle A of the GDPR.

Confidentiality Advisory Group advice conclusion

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

Request for further information (Summary)

1. The retention period for the NHS numbers of patients who have declined participation or not responded to the invitation request should be reduced – confirmation is required of the revised retention period. If it is determined that the ongoing retention of this information is required for the five year period cited, a stronger rationale should be provided to support this, together with an explanation of how this ongoing retention is compliant with current data protection legislation and the Information Commissioner's Office Guidance around non-response.
2. Patient and Public Involvement and Engagement – further information is required in this area to address the following points:
    a. Further work should be undertaken to the acceptability of the revised recruitment methodology, and the requirement to process confidential patient information with support under the Regulations, with an appropriate group. An overview of the activity which was carried should be provided, together with detail of the feedback provided. If the responses given were negative, the CAG would take this into account would take this into account when considering whether support can be recommended, or whether further actions are necessary.
    b. Feedback should be provided from the activity which has been directed in this area by Public Health England.
3. Patient Notification and Dissent – further action is required in this area to address the following points:
    a. A project-specific notification is required which provided clear information around the revised recruitment process for the study, explaining which organisations are involved and the items of confidential patient information used to facilitate this and to include a project-specific dissenting mechanism,
    b. Confirmation is required of where this information would be displayed,
    c. It is recommended that the revised communication materials are reviewed as part of the further patient and public engagement activity,
    d. An overview should be provided around how the project-specific objection mechanism would be operated to ensure any dissent is respected.
4. The patient recruitment materials should be revised to include a clearer explanation of the recruitment process and how a patient has come to be invited to participate in the study and provide clear information around how an objection to the use of data can be raised.
5. Confirm what lawful basis is being relied upon for the processing of data and special category data in order to show compliance against principle A of the GDPR. Further information can be found on the HRA website at the following link: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed - NHS Digital, Public Health England and**

University of Cambridge – School of Clinical Medicine all have a published satisfactory reviewed grade on V14.1, 2017/18).

d. 18/CAG/0145 – Synergy between PCI with TAXUS and Cardiac Surgery: SYNTAX Extended Survival (SYNTAXES) 10 year follow-up

Purpose of application

This application which has been submitted by University Hospital Southampton NHS Foundation Trust on behalf of the Erasmus Medical Center (based in Netherlands), set out the purpose of medical research which aims to undertaken a ten year follow-up of patients who participated in the SYNTAX trial. The SYNTAX trial was the first large-scale randomised controlled trial which investigated Coronary Artery Bypass Grafting (CABG) versus Percutaneous Coronary Intervention (PCI) with drug-eluting stents in patients with coronary artery disease. The study follow-up completed at five years follow-up; however, questions remain outstanding around which of the two treatments provided better outcomes for patients within the trial. This application proposes undertaking a non-interventional 10 year follow-up of patients who were enrolled in the trial via NHS administrative datasets.

The follow-up will be coordinated by University Hospital Southampton NHS Foundation Trust on behalf of all sites within England and Scotland. Confidential patient information in relation to the study participants will be disclosed from the seven English sites to the named applicant at University Hospital Southampton NHS Foundation Trust, who will coordinate the follow-up process via NHS Digital. Alternative arrangements will need to be made by the applicant in relation to the Scottish site.

A recommendation for class 1, 2, 3, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

All 245 patients who participated in the SYNTAX trial, in England.

The following items of confidential patient information are required for the purposes stated:

- Name – sample validation and linkage,
- NHS Number – sample validation and linkage
- Hospital ID – sample validation,
- Date of birth – sample validation and linkage,
- Date of death – analysis,
- Gender – analysis,
- Study ID – sample validation and linkage.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the project defined an appropriate medical purpose through medical research. It was agreed that there was a strong public interest in the proposed 10 year follow-up of patients from the historical trial, due to the questions which remained outstanding from the completed trial around the safety and efficacy of the two treatments which were trialled.

Practicable alternatives

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

- Feasibility of consent

The Group noted that the purpose of the project was to follow-up the mortality status of patients who were previously enrolled in the consented study. It was agreed that it was not feasible to seek consent for this activity.

- Use of anonymised/pseudonymised data

Confidential patient information is required to facilitate the linkage by NHS Digital, which could not be otherwise achieved.

Data Flows

It was proposed within the application that confidential patient information would be disclosed from the seven English study sites which participated in the previous trial to University Hospital Southampton NHS Foundation Trust, which was acting as a central coordination site for the purposes of the application to NHS Digital. A query had been raised with the applicant in advance of the meeting around this proposed data flow, as it was noted that the processing of confidential patient information under the Regulations could be limited if sites disclosed information directly to NHS Digital. An interim response was provided by the wider study team to this query; however, it was noted that the main applicant had not confirmed that rationale provided. The Group agreed that the query would be raised as part of the formal outcome, to enable the main applicant to provide a justification to this wider information access.

Members agreed that confirmation was required that the dataset returned by NHS Digital following linkage would be pseudonymised by study-ID only.

Justification of identifiers

The CAG agreed that the items of confidential patient information requested was appropriate and proportionate to facilitate the proposed linkage and analysis.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Clarification was required around when the confidential patient information would be deleted by NHS Digital and University Hospital Southampton NHS Foundation Trust.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The application did not describe any activity in this area. Members agreed that work should be undertaken in order to test the views of an appropriate patient and public group around the use of confidential patient information without consent in order to facilitate the 10 year follow-up. It was suggested that this could be undertaken with a patient group associated with the lead site in Southampton. Feedback would be required prior to any recommendation of support coming into effect. If the responses given were negative, the CAG would take this into account when considering whether support can be recommended, or whether further actions were necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that 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 2018. The applicant had stated that the sites would be encouraged to display information about the study follow-up on their websites; however, a copy of the text was not provided. It was agreed that a copy of this document was required for consideration together with confirmation that the sites would be required to display the information. An appropriate dissenting mechanism had been described, which enabled patients to contact their treating clinician of the lead site to object to the use of their data; however, as the document text had not been provided, it was unclear how this would be described to patients.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. Confirmation is required that a favourable ethical opinion is in place for the project prior to any final recommendation of support coming into effect.

Additional Points

The Group recommended that the applicants consider ways in which to future-proof consent taken around follow-up in wider trials, to ensure that there is a mechanism in place to facilitate follow-up without the requirement to seek support under the Regulations to facilitate this.

Confidentiality Advisory Group advice conclusion

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

Request for further information (Summary)

1. Provide further justification to explain why confidential patient information will be disclosed to the University Hospital Southampton NHS Foundation Trust site, prior to onward transmission to NHS Digital.
2. Confirm that information would be returned from NHS Digital in a pseudonymised format with Study-ID alone.
3. Confirm at what stage confidential patient information retained with support under the Regulations would be deleted by NHS Digital and University Hospital Southampton NHS Foundation Trust, in order to clarify the duration of support which is required under the Regulations.
4. Patient and public engagement activity should be undertaken to test the acceptability of using confidential patient information without consent for the application purpose. An overview of the activity undertaken and the feedback provided is required prior any recommendation of support coming into effect.
5. Patient Notifications and Dissent – provide a copy of the text which will be displayed on the historic site website in order to raise the profile of this proposed follow-up study. This should also describe how patients can object to the use of their information for these purposes. Confirmation should also be provided that all historic sites have confirmed that they will display this information of their websites as part of the communications strategy to support the follow-up study.

Recommendation:

The following point is added as a recommendation only and does not require formal response to the CAG in relation to this application.

1. It is recommended that the applicant considers ways to futureproof consent for any future studies in order to facilitate follow-up without the requirement for support under the Regulations.

Specific conditions of support (Provisional)

1. Support extends to the English sites only.
2. Favourable opinion from a Research Ethics Committee (**Pending**).
3. Confirmation from the IGT Team at the NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed - University Hospital Southampton NHS Foundation Trust and NHS Digital show a published satisfactory reviewed grade on V14.1, 2017/18**).

6. NEW APPLICATIONS – Non-Research

a. 18/CAG/0147 – National Adult Community Acquired Pneumonia Audit 2018-19

Purpose of application

This application from the British Thoracic Society set out purpose of a national audit programme into community acquired pneumonia in adults. The first British Thoracic Society (BTS) CAP audit took place in 2009/10, with re-audits in 2010/11, 2011/12, 2012/13 and 2014/15. The standards for the audits were derived from the 2009 update to the BTS Guidelines for the management of community acquired pneumonia in adults (the 'BTS Guidelines'). Over the years, a total of over 120 acute trusts have participated in the audit, involving over 24,000 cases of pneumonia.

To date, the CAP audit has not collected confidential patient information so has not required support under the Regulations. Data from the audits have shown a decreasing trend in mortality from CAP associated with improved processes of care. There is however evidence from GP databases and from HES data that variation in care of adults hospitalised with pneumonia exists across the UK. Previous BTS CAP audits have not assessed variation between sites. In contrast, recent national UK audits in both lung cancer and COPD have compared performance between sites to assess for variation in care and outcomes.

The aim with the BTS CAP audit 2018/19 is to assess variation in the care of patients hospitalised with pneumonia in the UK and seek explanations for any variation observed. In order to increase the value and data quality of the audit, it is proposed to link the BTS CAP audit data to routinely collected HES and ONS data. The BTS CAP audit dataset is rich in process of care measures whilst the HES dataset is strong in relation to patient baseline parameters and hospital outcome measures, but fails to capture CAP process of care measures. Linkage of these data sources will enable:

1. Analysis of variation of care according to a wider range of important outcome measures, including mortality, ICU admissions, hospital re-admissions and healthcare costs.
2. Improved case-mix adjustment of the audit cohort according to underlying co-morbidities and socio-economic parameters.
3. Health economic analyses.

The core aim of the project is to drive improvements in care, particularly in relation to the quality improvement objectives identified in 2014/15, by allowing participants to monitor their progress against these targets. In this round of audit (2018/2019) additional information will be provided on where variation exists in relation to these targets and performance generally, to allow sites to identify where quality improvement initiatives are needed locally.

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

Confidential patient information requested

Cohort

The study population is hospitalised adults (16 years or older) admitted with a clinical radiographic diagnosis of Community Acquired Pneumonia (CAP) from 1 December 2018 to 31 January 2019. 150 Trusts are expected to participate in the audit and will be asked to enter as many cases as possible, with a minimum requirement of 60 cases per Trust. Limited information will be collected on patients who are deemed ineligible for inclusion in the audit; however, these patients are out of scope as confidential patient information will not be requested.

The following items of confidential patient information will be entered into the audit platform to facilitate linkage with HES and ONS datasets by NHS Digital:

- NHS Number,
- Home Postcode,
- Sex,
- Date of birth,
- Date of death.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was through the management of health and social care services. It was recognised that the audit had not previously collected confidential patient information. The change in methodology was brought about due to the considerable variation outcomes which were reported by the audit that could not be fully explored from the anonymised data previously collected. Members were assured that there was public interest in the activity proceeding and were satisfied that the change in methodology had been sufficiently justified.

Clarification of Scope

The Group acknowledged that patients eligible for inclusion in the audit were retrospectively identified following review of their diagnosis. Confirmation would be requested from the applicant that this diagnosis review would be undertaken by a member of the direct care team, to ensure that the recommendation of support which was required under the Regulations was not intended to extend to this activity.

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 provided a clear and justified rationale to support why consent was not feasible for the project, including retrospective analysis of patient diagnosis, potential for patients to have been discharged from the hospital prior to their diagnosis, cohort size, necessity for full coverage and the additional burden that a consenting mechanism would put on clinical teams. The Group recognised that the applicant had undertaken a detailed assessment and was assured that consent was not feasible for the audit.

- Use of anonymised/pseudonymised data

Processing of confidential patient information was required to facilitate the linkage with wider datasets held by NHS Digital that could not be otherwise achieved.

Justification of identifiers

Members were assured that the items of confidential patient information requested were appropriate and proportionate to the proposed activity.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. It was confirmed that confidential patient information would be retained for a 12 month period following the close of the audit in order to facilitate linkage via NHS Digital, following which time this would be destroyed. The applicant explained that it took 30 days to complete the deletion of data from backup servers, so the deletion process would commence at 11 months from the close of the audit to ensure that all data was destroyed within the agreed 12 month timeframe. The Group raised no issues with the proposed exist strategy.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The application explained that the British Thoracic Society (BTS) audits were overseen by the BTS Quality Improvement Committee and BTS Information Governance Committee (IGC). The IGC membership included patient representation through the BTS Lay Trustee, to ensure that patient perspectives were taken into account across BTS work.

Specific consultation in relation to this proposed audit was undertaken with the Nottingham Pneumonia Patient and Public Involvement Group in May 2018 and a specific feedback document was provided within the application submission. The applicant further explained that once the audit was launched, a patient/public representative would be identified to provide continued input into the audit.

The Group agreed that the activity which had been undertaken within the preparatory stages of the audit was of a high standard. Whilst the appointment of a specific lay representative to provide continued input to the audit was commendable, Members agreed that further work should be planned in this area, utilising the established links with the Pneumonia group, to be undertaken as the audit progressed. Feedback on the actual activity carried out would be required at the time of first annual review. If the responses given were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that 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 2018. The Group considered the posters and leaflets which had been provided to facilitate the patient notification mechanism. These were agreed to be appropriate and it noted that dissent could be raised by contacting treating clinicians or the audit team directly. No issues were raised in this area.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed scores for British Thoracic Society and Westcliff Solutions Ltd had been published in

respect of version 14.1 (2017/18) of the toolkit; however, these self-assessments had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. This would need to be addressed by the applicant.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the General Data Protection Regulation (GDPR) and Data Protection Act (DPA) 2018. Further information is required from the applicant to confirm what lawful basis was being relied upon for the processing of data and special category data in order to show compliance against principle A of the GDPR.

Confidentiality Advisory Group advice conclusion

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

Request for further information

1. Confirm that the patient diagnosis review would be undertaken by a member of the direct care team.
2. Confirm what lawful basis is being relied upon for the processing of data and special category data in order to show compliance against principle A of the GDPR. Further information can be found on the HRA website at the following link: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/

Specific conditions of support (Provisional)

1. Patient and Public Involvement and Engagement strategy should be extended to enable additional activity to be undertaken as the audit progressed. An overview of the actual activity which has been carried out, together with details of the feedback provided, should be provided at the time of first annual review. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Pending - British Thoracic Society and Westcliff Solutions Ltd required NHS Digital review of V14.1, 2017/18**).

7. MINUTES OF THE MEETING HELD ON 05 JULY 2018

The minutes of the CAG meeting held on 05 July 2018 were received and confirmed as an accurate record of proceedings with no amendments or revision required.

8. CAG CHAIR REPORT

The CAG received a report from the Chairman for August 2018.

9. ANY OTHER BUSINESS

The Group had a general discussion around potential future educational items which was recorded for management by the office.

An update was provided around the vacancy recruitment for the Confidentiality Advisor post within the Confidentiality Advice Team. It was noted that interviews were scheduled for week commencing 17 September 2018. Further information would be provided in due course.

No further business was raised.

The Chair thanked Members for their time and the meeting was closed.