Health Research Authority

# Minutes of the meeting of the Confidentiality Advisory Group

## 25 January 2018 at Barlow House, Manchester

**Group Members:**

| *Name* | *Present* | *Notes* |
|---|---|---|
| Dr Malcolm Booth | Yes | |
| Ms Sophie Brannan | Yes | Lay |
| Dr Tony Calland MBE | Yes | Chair |
| Dr Patrick Coyle | Yes | Vice Chair |
| Mr Anthony Kane | Yes | Lay |
| Dr Rachel Knowles | No | Apologies received |
| Professor Jennifer Kurinczuk | Yes | |
| Mr Andrew Melville | Yes | Lay |
| Dr Murat Soncul | Yes | Alternate Vice Chair |

**Also in attendance:**

| *Name* | *Position (or reason for attending)* |
|---|---|
| Ms Natasha Dunkley | Head of the Confidentiality Advice Service |
| Miss Kathryn Murray | Senior Confidentiality Advisor |
| Mr Dave Murphy | Observer – HRA Communications Manager |

## 1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introduction

The Chair welcomed Mr Dave Murphy, HRA Communications Manager, to the CAG meeting who was in attendance in the capacity of an observer, in order to gain an understanding of the CAG.

Apologies for Absence

Apologies for absence were received from Dr Rachel Knowles ahead of the meeting.

Declarations of Interest

There were no declarations of interest made in connection with the application activity scheduled for consideration.

## 2. APPROVAL DECISIONS

The following was shared with the CAG for information.

Secretary of State Approval Decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the **23 November 2017** meeting applications.

HRA Approval Decisions

The HRA agreed with the advice provided by the CAG in relation to the **23 November 2017** meeting applications.

## 3. INTRODUCTION FROM THE CHAIR – Dr Tony Calland

Dr Tony Calland, newly appointed Chair of the CAG, provided an introduction to the meeting.

## 4. ANNUAL REVIEWS

### a. ECC 5-05 (a)/2012 Clinical Practice Research Datalink Service (CPRD) Annual Review

**Context**

This application is a unique research application that could be considered to provide an 'honest broker' or 'safe haven' processing environment. The CPRD is a function of the MHRA. Due to its national nature, the annual review is considered at full CAG meetings. The application sets out the activity to process a broad range of specified datasets by NHS Digital, and to enable de-identified disclosures to research applicants by the CPRD, following advice from their ISAC group.

At a high level, support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 has been provided for the following aspects:

- GP practices and specified others (according to the approved 'Master Dataset' list) to transfer confidential patient information to NHS Digital.
- NHS Digital to receive identifiers, undertake linkages and provide the CPRD a de-identified dataset.

- NHS Digital is operating under the direction of the MHRA (via CPRD). The applicant for the purposes of this application is the CPRD who are responsible for the actions of NHS Digital (who in turn are operating under instruction of the CPRD).
- The CPRD do not receive identifiable data from NHS Digital or others under the terms of this support. Any processing by CPRD of confidential patient information must rely upon another legal basis.

**Confidentiality Advisory Group Advice**

Response to Requested Updates

Members noted the update provided against correspondence arising from the previous annual review submission, and welcomed the requested update. In terms of communications to general practices, the review confirmed that CPRD needed to await the outcome of NHS Digital's ongoing work with the Understanding Patient Data Initiative (UPDI) on how to best communicate with the general public. It was indicated this was also dependent on finalising the new consent opt-out model in 2018, following the Government's acceptance of the National Data Guardian's (NDG) 2016 Review on Data Security and Consent Opt-outs. CPRD provided an assurance that, when these pieces of work are complete, CPRD will adopt wording agreed by the Department of Health and NHS Digital (as informed by the UPDI) to explain patient opt-outs and fair processing under data protection requirements that aligns with NHS Digital transparency statements.

Members noted and understood the dependencies, and agreed that while it was extremely important to ensure consistency, that it is a standard condition of this specific support that opt-out is respected, therefore members requested that CPRD provide a copy of the intended communications to the CAG. This should be provided no later than three months following agreement from the Department of Health, as informed by the UPDI, and in line with the timescales for rollout of the national opt-out model.

In terms of free text information, CPRD provided an update that, following advice from the Information Commissioner's Office in 2014, the CPRD had committed to destruction of any GP medical notes (referred to as 'free text') that had been incidentally collected by CPRD within relevant primary care patient records. Noting this was primarily a data protection compliance matter as the disclosure had not taken place under Regulation 5 support as a draft application had been withdrawn at the time, the CAG had previously requested a date by which this would be completed, and CPRD re-confirmed this would be completed no later than 17 February 2018. Members welcomed this definitive position and requested formal confirmation of the destruction of all of the incidentally collected free text information, to be provided no later than 20 days following 17 February 2018.

Practicable Alternatives

Members considered whether there were any new practicable alternatives to the disclosure of confidential patient information without consent, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Use of anonymised/de-identified information

It was confirmed that the support in place is provided to enable NHS Digital, as CPRD's Trusted Third Party (TTP), to receive and process a defined and minimum number of personal identifiers (NHS number, full date of birth, postcode, gender), without breaching the common law duty of confidentiality. These are directly provided to NHS Digital by participating GP's system providers. The identifiers enable the linking of CPRD primary care records to a wide range of secondary datasets relating to the provision of care and public health in England, as set out in CPRD's Master Dataset List. Secondary datasets routinely linked include NHS Hospital Episodes Statistics, PHE cancer registration data and defined Office for National Statistics (ONS) death registration data.

NHS Digital provides this linkage service to CPRD. As CPRD cannot receive confidential patient information under the support, patient confidentiality is protected through the service NHS Digital provides. CPRD has selected the procedure that uses only the minimum number of defined identifiers required to flow from GP system providers to NHS Digital. The procedure guarantees accurate linkage between primary care and chosen secondary datasets, prior to de-identification by NHS Digital and subsequent secure transfer of the de-identified linked data from NHS Digital to CPRD.

Members welcomed this succinct explanation and agreed that this appeared to be appropriate.

- Feasibility of consent

Due to the large numbers involved, approximately 16.7 million patient records, that are extracted by GP system providers and provided to NHSD, CPRD confirmed that it would not be feasible to contact patients individually to obtain consent. It was also confirmed that the CPRD governance and ethics model requires it to operate at arm's length from the patient and therefore CPRD is not able to identify patients directly from information provided by GPs or by NHS Digital. Attempts to contact patients by CPRD would inevitably lead to further disclosure of patient information that was not considered appropriate.

Justification of Identifiers

The annual review confirmed that CPRD has not elected to ask NHS Digital or CAG to use other identifiers such as full name and address, to use for data linkage purposes. Four data fields (as noted above) continue to be extracted from the GP Electronic Health Record to ensure appropriate matching takes place. It was confirmed that a high proportion of accurate matching of primary care to secondary care patient records can be achieved using only NHS number. However in some cases this may not exist or cannot otherwise enable matching. Date of birth, gender and post code are therefore also collected and used to validate and accurately match primary care data to secondary care data records, including in cases where no NHS number is available. Removal any of the four defined identifiers from the matching algorithm would prevent accurate linking of a primary care record to the appropriate secondary data record.

Date of Death Registration Data

The annual review confirmed that, on behalf of ONS, NHS Digital provides date of death registration data, which is considered '"personal disclosive", to CPRD. The review stated that ONS and NHS Digital have approved the legal basis for CPRD to access this data under s42(4) of the Statistics and Registration Service Act 2007 (as amended by s287 of the Health and Social Care Act 2012). ONS data, where this is included in linked data, is anonymised by CPRD before external release to researchers. ONS confirmed with CPRD their continued authorisation to release anonymised linked data, via email to CPRD on 31 May 2017.

It was unclear to members whether support under Regulation 5 was necessary to include date of death as per the originally approved application, based on the information submitted to the CAG, and requested clarification so that the legal basis and scope of the current application was clear in relation to death registration information.

Security Assurance

Members noted that version 14 of the Information Governance Toolkit had been provided for the CPRD. Separate checks confirmed that version 14 of the Information Governance Toolkit for NHS Digital, as they are the entity authorised to process confidential patient information for the purposes of this application, had been reviewed and confirmed as satisfactory.

Public Interest

The annual review confirmed that data provided by CPRD has been used in more than 1800 peer-reviewed publications aimed at improving public health, and that CPRD-based research had been used extensively to inform drug safety, clinical guidelines and best practice.

Based upon its considerations above, the CAG agreed that there was a public interest in this activity continuing, in terms of supporting the purposes behind the establishment of the CPRD and in allowing the provision of de-identified information for the purposes of key research through the support under Regulation 5.

**Confidentiality Advisory Group Advice Conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in this activity continuing, and therefore advised recommending support to the Health Research Authority, subject to compliance with pre-existing standard conditions, and the specific conditions of support as set out below.

**Specific Conditions of Support**

1. Applicant to formally confirm, within 20 days from 17 February 2018, that all incidentally collected free text information has been securely destroyed.

2. Applicant to provide an information update to the CAG on the communications to be utilised, no later than three months following agreement from the Department of Health, as informed by the UPDI.

3. Applicant to confirm within 20 days of this letter whether date of death registration data is now excluded from scope of support under Regulation 5, as the review indicated there to be another legal basis in place to support processing of this information.

4. Version 14 of the Information Governance Toolkit, in relation to NHS Digital, was reviewed as satisfactory by NHS Digital at 92%.

**b. PIAG 03(a)/2001 - National Cancer Registration and Analysis Service (NCRAS) Annual Review**

**01/03/2018: the Secretary of State for Health and Social Care had provided notification of additional time required to consider the CAG advice. At the time of publication of the ratified meeting minutes, confirmation had not been received from the senior civil servant on behalf of the Secretary of State for Health and Social Care whether they had accepted the CAG advice. The minutes published are an accurate reflection of the CAG advice given to the decision-maker.**

**Update 06/03/2018: The Secretary of State for Health and Social Care confirmed 02 March 2018 they were satisfied with the CAG advice, but requested additional focus in the outcome on the following points:**

- **Revisions advised under 'Patient Information Leaflet' on page 4 of the draft outcome to be revised more urgently and ideally for May 18;**
- **Under the 'Specific conditions of support', the cleaning up of the register needs to be done without delay; and**
- **CAG need to see a revised information leaflet immediately.**

**The outcome has been revised in accordance with this decision, and minutes re-published to reflect the points made by the decision-maker.**

**Annual Review Submission**

The review provided an update against the previous queries the CAG had raised regarding the previous annual review. This consisted of clarifications regarding how PHE defined identifiability, the approach to transparency of information disseminated, information on the role of the Office for Data Release, and clarification of the terminology used by Public Health England when describing levels of identifiability in the data release register.

**Confidentiality Advisory Group Advice**

Members focused primarily on the annual review form and the applicant responses to queries that were raised prior to consideration.

Telegraph Article

Members noted the recent Telegraph article that, following a freedom of information request, had raised concerns about a disclosure of cancer registration information. Members noted this as it technically involved information processed under Regulation 2 of the COPI Regulations. PHE had subsequently written directly to CAG and confirmed that they accepted the information provided in the data release register regarding the release was unclear, and that the disclosure was aggregate information anonymised in accordance with the Anonymisation Standard. Members noted this update and the fact the disclosure related to anonymised information, and did not comment further on this aspect.

Language used to describe identifiability

In reviewing the responses provided in response to previous queries regarding terminology in standard operating procedures, Members agreed that they found the definitions used to be unclear and inconsistent, and not aligned with the PHE data release register. The response provided indicated that PHE utilised the terms '*identifiable'*, '*potentially identifiable'*, and '*anonymised*. However, the data release register referred to '*personally identifiable'*, *de-personalised'* and '*anonymised'*, so there appeared to be inconsistencies within internal and external documentation, that members agreed would be confusing to the public and those operating within the framework.

In particular, members questioned the use of '*potentially identifiable'* as they found it to be unclear as to what it referred to, and there was no clearly understood definition. Members advised that use of this term should be halted, particularly in relation to any disclosures made under the Regulations, as it was not a widely accepted or known definition and it did not aid in supporting transparency for the general public.

Members highlighted that, where the legal basis for disclosure is under the Health Service (Control of Patient Information) Regulations 2002, there is a statutory definition of '*confidential patient information'* that underpins the operation of the Regulations as it confirms what information falls within the remit of these Regulations. Members advised that care should be taken when using other definitions as it can cause confusion from the original statutory language, and inconsistencies.

Following on from these points, the response to queries set out how PHE intended to refer to disclosures made to the CPRD (MHRA) as follows: "*PHE will be amending subsequent releases of its register to state that confidential patient information, rather than de-personalised data, is being released to CPDR and NHS Digital under the CPRD Regulation 5 approval*".

Members noted this suggestion remained inaccurate as it states that CPRD are receiving confidential patient information and therefore advised the following, or suitable variant, should be published:

> *Under Regulation 5 of the COPI Regulations, confidential patient information is disclosed to NHS Digital who are acting on behalf of CPRD. CPRD does not receive confidential patient information under this Regulation 5 support.*

The CAG noted that any references to CPRD receiving confidential patient information under their support are inaccurate and misleading to the general public and general practices, and must be avoided in any external communications to avoid understandable confusion.

Office for Data Release and Transparency

Members noted the responses given and agreed that they found the lines of accountability confusing. Members requested a diagram that sets out the organisational structures referred to, lines of accountability, and details of the names and roles of the people involved.

It was noted that there did not appear to be any lay involvement, which members understood to be typical in these types of activities. While not a specific condition, members advised that PHE should consider the benefits and different perspectives genuine lay representation could bring, in order to support public confidence and transparency.

Patient Complaint

Members were advised that the advice team had been copied into correspondence between a third party and Public Health England. The CAG did not consider the specific detail of the complaint as it would not be appropriate at this stage, but reminded Public Health England that under the COPI Regulations, and specifically the section that sets out restrictions and exclusions, that those operating within an approval are under a statutory obligation as follows:

> (7)(1)(e) *on request by any person or body, make available information on the steps taken to comply with these Regulations*.

Members therefore reminded the applicant there is an obligation to respond in accordance with this requirement when questions are raised regarding the support, and these should be responded to sympathetically and concisely.

Patient Information Leaflet

Members noted that a new cancer registration leaflet had been produced and a revised version published in October 2017. Its development was indicated to be overseen by a working group comprised of representatives from CRUK, Macmillan, the Teenage Cancer Trust and UseMyData. Members welcomed development of the leaflet, however, raised a number of points.

Members commented that the leaflet had been simplified to the extent that it was no longer clear, particularly that the collection of cancer registration information is separate to that of the normal patient record. It also indicated it was only used for healthcare purposes, which differs from research. Members could not identify from the leaflet an understanding as to what information was collected, no clear statement of the purposes to which the information will be used, and particularly no mention of the fact that confidential patient information is released to third party researchers and supports a number of research activities, including recent work the CAG is aware of in terms of PHE's developing role in relation to recruitment into clinical trials and source data verification. Members noted that, particularly in light of the forthcoming requirements of transparency in the new Data Protection Act from May 2018 that this should be reviewed and made much clearer as to the purposes so as to be accurate.

Members welcomed steps to be taken to increase awareness and encouraged further consideration of possible means and existing communication mediums to inform as many patients as possible.

**Confidentiality Advisory Group Advice Conclusion**

The CAG agreed that the applicant had demonstrated there was a continuing public interest in support continuing in its current form and therefore provided a positive recommendation to the Secretary of State for Health and Social Care and the Health Research Authority, subject to the conditions set out below.

**Specific Conditions of Support**

1. Assessment and implementation of consistency, precision and accuracy of public-facing language used when describing disclosures, especially in relation to disclosures made under the Regulations. Removal of inaccurate references to CPRD receiving confidential patient information in accordance with advice from the CAG.

2. Provision of a clear organisational diagram that sets out names, roles and lines of accountability for the Office for Data Release and supporting structures.

3. PHE to ensure it responds to relevant enquirers in accordance with Regulation 7(1)(e)

4. Patient information leaflet to be reviewed in light of CAG advice to make clear the purposes to which the information will be processed. The CAG would expect to see a revised information leaflet at time of next annual review that adequately explains the numerous purposes to which PHE use the information.

5. The processing of confidential patient information for the purpose of genetic counselling is managed entirely by PHE without reference to advice by the CAG, therefore further general reference to this aspect should no longer be included in future annual reviews as this is out of the scope of the CAG review.

6. Maintenance of a continuing satisfactory level of security assurance for the duration of the support, as evidenced through publication of satisfactory review by NHS Digital in relation to the current Information Governance Toolkit (and future changes under the IGT replacement). Applicant to ensure they provide complete evidence of <u>one</u> relevant security assurance specific to this activity in future annual reviews.

## 5. AMENDMENTS

### a. PIAG 03(a)/2001 - National Cancer Registration and Analysis Service (NCRAS)
**Amendment Request**

This amendment described the intention to include additional information around patients who had participated in a clinical trial of cancer therapies to be flagged within the registry. This will include all cancer patients who enrolled on a trial starting from 1986 onwards. The following additional information would be included within the registry:

- Trial Reference
- Trial Centre
- Date of trial recruitment.

Processing of the following data items, which are already known to the registry, will be required to enable PHE to link the clinical trial information to the correct patient within the registry:

- Name
- Address
- Date of birth
- Gender
- NHS Number of these patients.

It was clarified that Public Health England did not intend to include any clinical or research data collected on these patients within the registry.

**Confidentiality Advisory Group Consideration**

Members noted that an amendment had been submitted that specified changes to 'data flows'. Specifically, it requested flagging in the cancer registry of patients who have participated in a clinical trial of cancer therapies. It was indicated there is evidence that cancer patients taking part in clinical trials or treated in research-active oncology units experience better outcomes, and this evidence is based on limited numbers of patients from selected trials as it is currently not possible to identify systematically at a national level all cancer patients who have participated in a clinical trial and assess the local and trial-specific factors that may affect uptake. It was indicated that inclusion of information on trial participation in the cancer registry will enable PHE to monitor trial recruitment systematically across trial centres and improve the opportunities for more cancer patients to be included in clinical trials of cancer therapies.

In reviewing the information, the specific nature of Regulation 2 was discussed and responses from Dr Kyffin were noted; Members indicated that if PHE were of the view that the activity already fell within the specified purposes set out in Regulation 2, they were unclear why this had been submitted as an amendment. It was understood that applications approved under Regulation 5 were bound by the detail of the approved application and therefore any changes underwent a formal amendment process. As Regulation 2 already set out the purposes for which cancer registration information could be processed without consent, and if after PHE had undertaken their internal assessments and due diligence checks, and were satisfied that the activity fell within the prescribed purposes, then the expectation would be that the activity would be submitted as part of the standard annual review.

Members agreed that the activity was entirely laudable, noted the information provided, and raised no further comments.

**b. 16/CAG/0056 – Learning Disabilities Mortality Review Programme**

**Context**

<u>Purpose of Application</u>

This application from University of Bristol set out the purpose of the Learning Disability Mortality Review (LeDeR) Programme as a service improvement initiative. It was commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England.

The aim of the programme was to drive improvement in the quality of service delivery for people with learning disabilities (LD) and help to reduce premature mortality and health inequalities in this population. The remit of the LeDeR Programme was primarily to support local agencies to review deaths of people with learning disabilities and to use the learning gained to make improvements in the delivery of care. The LeDeR programme will develop and roll out a standardised process for reviews to support this local delivery, and provide strategic support for its implementation. In doing so, it will be building on the well-established practice in health and social care of conducting mortality reviews as a means of improving patient care.

The anonymised mortality case reviews will be collated and evaluated by the programme team to ensure that learning is being embedded in practice. This will be reported on annually. Reports on the findings of this work will be disseminated to regulators, policy makers, commissioners, service providers, practitioners and patient and family groups with the aim of supporting changes that improve the quality and safety of care for people with learning disabilities.

A recommendation for class 1, 4, 5 and 6 support was requested to allow the disclosure of confidential patient information from:

- The reporting of personal details about people with learning disabilities who have died from 1st April 2015 to 31 May 2018 to the LeDeR Programme
- Collection of detailed case information and review of health or social care case notes in order for a local reviewer to conduct a review of the death
- To share NHS numbers (or other key identifiers) with the Office for National Statistics to obtain the ICD10 codes for each person's causes of death.

**Amendment Request**

The amendment requests support for the following two changes:

1. Redacted, rather than pseudonymised, information to be sent to Steering Groups – which would involve the sharing the initials and NHS number of the patient where necessary, plus the name of relevant professionals, agencies, organisations and care providers sufficient to enable recommendations to be addressed.
2. The Learning Disability Mortality Review team to be able to store the data in this redacted form for the 10 year period.

**Confidentiality Advisory Group Advice**

Public Interest

The CAG acknowledged there was a strong public interest in the application activity; however, it was noted that learning points from the case reviews which had been undertaken were not currently being implemented as staff at the sites were unable to target the learning points due to the receipt of data in an anonymised format.

Whilst it was acknowledged that there was potentially an increased risk of re-identification of the deceased patient from the redacted data set, Members were assured that this risk was outweighed by the potential future benefit for patients with learning disabilities from the implementation of learning points from the care reviews.

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 e.g. month and year instead of full date of birth.

The Group discussed the proposed redaction process which would be applied to the data included within the case review information which is shared with local steering group. The CAG was assured that the inclusion of information around the clinics and departments involved, together with the patient's NHS Number was justified; it was not satisfied that patient initials needed to be included in this information. Members discussed this point further and it was commented that whilst NHS Number was a direct patient identifier, this was not directly identifiable outside of an NHS environment. It was noted that the patient's initials were potentially identifiable to a wider audience outside of the NHS environment due to the specialist patient cohort.

The CAG would provide a recommendation of support to the inclusion of information in relation to relevant professionals, agencies, organisations and care providers involved in the case, together with patient NHS Number within the redacted care review information which is shared with steering groups and retained by the programme team for the 10 year period. Support was not extended to the inclusion of patient initials.

Duty of Confidentiality

The CAG considered the terms of reference for the local steering groups which had been shared as part of the amendment application. Within the document, one the stated purpose/roles of the group was to ensure agreed protocols are in place for information sharing, accessing case records and keeping content confidential and secure. At a later section within the document, it was stated that the governance of the group was to be advised in line with the area governance arrangements. Members acknowledged that the redacted data that would be shared as part of the case review would not contain any confidential patient information; however, due to the increased risk of the redacted data set, it was recommended that these roles be revisited to ensure that the data is appropriately handled to ensure security and confidentiality.

**Confidentiality Advisory Group Conclusion**

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

**Specific Conditions of Support**

1. Support is extended to the transfer of redacted information to be sent to Steering Groups – this would include the NHS number of the patient where necessary, plus the name of relevant professionals, agencies, organisations and care providers to enable the case review recommendations to be implemented.
2. Support is extended to allow the Learning Disability Mortality Review team to retain data in this redacted form for the 10 year period.
3. Confirmation of suitable security arrangements via IG Toolkit submission - **(Confirmed - Version 14, 2016-17, reported a reviewed satisfactory score at 92%).**

Recommendation:

1. It was recommended that the terms of reference for the local steering groups be revisited to ensure appropriate protocols are in place to ensure the confidentiality of the data.

## 6. NEW APPLICATIONS – Research

### a. 18/CAG/0002 – Associations between Diabetes and Education

**Context**

Purpose of Application

This application from Cardiff University set out the purpose of medical research aiming to better understand the effects of diabetes on educational outcomes. It was acknowledged that education may also have an impact on an individual's diabetes management. The applicants have an interest in how other factors influence the relationships between health and education, these include characteristics of the child (e.g. gender), their families (e.g. single parent families), and the health services they use (e.g. type of diabetes clinic). The project aims to use linked health and education records to quantify the associations between differences in levels of HbA1c (an indicator of longer-term blood glucose levels) and educational outcomes.

The application involves the disclosure of confidential patient information from both the National Diabetes Audit (Adults – England) and National Diabetes Audit (Adults – Wales) (held by NHS Digital) and the National Paediatrics Diabetes Audit (held by the Royal College of Paediatrics and Child Health) to NHS Wales Informatics Services (NWIS). Data will also be released from the Higher Education Statistics Agency (HESA) dataset to NWIS; however, this is out of the CAG's remit as it is not confidential patient information. Corresponding clinical data will be released direct to the Secure Anonymised Information Linkage databank (SAIL), which will then be linked with psedonymised demographic data.

The applicants clarified that HESA are providing all of the additional education data – for students in England and Wales at University plus school education data for students from English schools. The school education data for pupils from Wales is already provided by Welsh Government routinely into SAIL where is it is available in pseudonymised format for linkage to the new datasets.

The legal basis for the collection of National Diabetes Audit (England) is by Directions, National Diabetes Audit (Wales) the legal basis is "section 251" (Reference: 17/CAG/0124) and for the National Paediatric Diabetes Audit the legal basis is "section 251" (Reference: ECC 2-03(c)/2012).

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

Confidential Patient Information Requested

Cohort

All birth cohorts between 1983 and 2013 within England and Wales, for whom diabetes audit data (NPDA and NDA) from 2003 to 2018 and education data from 2003 to 2018 will be requested. It is anticipated that there will be 17,195 patients included within the project.

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

- NHS number – used to create anonymised linkage field,
- Date of birth – used to create anonymised linkage field, validation and translated for analysis (week of birth),
- Gender – validation and analysis,
- Postcode – validation and translated to LSOA for analysis.

Wider clinical information will be provided from the diabetes audits for inclusion in the analysis dataset.

**Confidentiality Advisory Group Advice**

Public Interest

The CAG was assured that the application defined a medical purpose through medical research and it was acknowledged that there was public interest in the research question, which aimed to gain an understanding of the relationship between diabetes and the educational attainments of children with the condition.

Scope of Support

The remit of the CAG set out in the Health Service (Control of Patient Information) Regulations 2002 applies to confidential patient information (as defined within the NHS Act 2006). The recommendation of support provided extended to the release of confidential patient information from the National Diabetes Audit (England), the National Diabetes Audit (Wales) and National Paediatric Diabetes Audit datasets only. It was noted that it was the responsibility of the data controller for the HESA education data to ensure that a legal basis had been established to support any disclosures from this dataset.

Practicable Alternatives

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

- Feasibility of consent

Members were assured that consent was not feasible for the proposal due to the sample size to be included.

- Use of anonymised/pseudonymised data

It was acknowledged processing of confidential patient information was required in order to link the relevant datasets. Analysis would be undertaken on an anonymised dataset.

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 e.g. month and year instead of full date of birth. The Group was assured that the items of confidential patient information requested were proportionate and justified in order to achieve the aims of the project.

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 acknowledged that the exit strategy from support under the Regulations was the anonymisation of the dataset for analysis. The applicants had asserted that the process of data linkage and anonymisation would be achieved within a six-month period of all relevant approvals being in place. Members acknowledged that there would be a lead-in time, prior to any data release whilst the applicants were seeking the relevant approvals. It was commented that, should the processing of confidential patient information extend beyond this period, submission of an amendment would be required to extend the duration of support provided under the Regulations.

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 activity which had been undertaken in this area was acknowledged, however, Members commented that there had been no engagement with children with diabetes who were now adults. The Group agreed that this was an important cohort and further activity should be undertaken to seek the views of this group.

It was further commented that the patient and public engagement activity which had been undertaken to date had not explored the acceptability of using confidential patient information without consent in order to establish the anonymous dataset which would be used for analysis. The Group agreed that further work would be required in this area to seek the opinions of patients and the public around the use of confidential patient information in the creation of the analysis dataset.

It was agreed that a report would be required at the time of first annual review around the additional activity which had been undertaken in this area. 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 and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Within the submission, the applicants had provided details of the patient notification materials of NPDA, NDA and HESA for information. It was noted that any individual who had registered a dissent against the use of their data with these three organisations would not be included within the project specific database established for this research.

The applicants had also provided project-specific notification materials, which would allow patients the opportunity to register their dissent against the use of their data within the project. It was identified that any project-specific dissent would need to be raised in advance of the data providers releasing information to NWIS and SAIL. Members considered this and agreed that the project-specific patient notification materials would need to be displayed with a lead-in time ahead of data release, to ensure that any objections received could be respected. The Group agreed that project-specific notifications should be displayed for a two month period, ahead of data release, to facilitate patient objections. The cut-off for receipt of project-specific objections would need to be added to section 'Opting out of the study'.

**Confidentiality Advisory Group Advice Conclusion**

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

**Specific Conditions of Support (Final)**

1. Support extends to the release of confidential patient information from the National Diabetes Audit (Adult – England) and National Diabetes Audit (Adult – Wales) (held by NHS Digital) and the National Paediatrics Diabetes Audit (held by the Royal College of Paediatrics and Child Health) to NHS Wales Informatics Services (NWIS).
2. Patient Notification and Dissent:
    a. Project-specific patient notification materials should be displayed for a two-month period ahead of any release of data from the National Diabetes Audit and the National Paediatric Diabetes Audit datasets, to facilitate patient objections.
    b. The section titled 'Opting out of the Study' should be updated to include confirmation of the cut-off date for the receipt of objections.
3. Patient and Public Involvement and Engagement – further work should be undertaken in this area to address the following points:
    a. Children who are now adults with diabetes, who will be included in the project should be approached about the study, in order to seek their views on the proposed activity,
    b. Further work should also be undertaken to seek the views of patients and the public around the acceptability of using confidential patient information as described in the application in order to establish the anonymous dataset to be used in analysis,
    c. A report should be provided at the time of first annual review around the actual activity which has been undertaken in this area, together with any feedback or outputs,
    d. 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.
4. Favourable opinion from a Research Ethics Committee (**Confirmed – 05/12/2017**).
5. Security Assurance Arrangements – **NWIS have provided a CPIP (Caldicott: Principles into Practice) report showing a 94% satisfactory assessment rate**.

**b. 18/CAG/0003 – FAST- Febuxostat versus Allopurinol Streamlined Trial V 19.0**

**Context**

Purpose of Application

This application from the University of Dundee sets out the purpose of medical research which aims to follow-up patients from a fully-consented CTIMP (Clinical Trial of an Investigational Medicinal Product) which was evaluating the most effective treatment for gout. Patient information will be sent from the study research team at the University of Dundee to NHS Digital in order for linkage with HES and ONS records, to collate hospital admission and death data.

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

Confidential Patient Information Requested

Cohort

All English patient participants recruited to the FAST CTIMP study. The sample size is 1834 patients.

The following data items will be transferred from University of Glasgow to NHS Digital:

- Name – validation and linkage,
- NHS number – validation and linkage,
- Date of birth – validation and linkage,
- Postcode – validation and linkage,
- Date of death – retained in full format for analysis,
- Cause of death – provided in ICD10 format for analysis,
- FAST-ID – linkage.

**Confidentiality Advisory Group Advice**

Public Interest

The CAG was assured that the application defined a medical purpose, which was in the public interest as it would enable the patient follow-up protocols from the consented trial of the investigational medicines to be completed.

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 acknowledged that all patients had provided consent to be involved in the initial study; however, a determination had been made by NHS Digital that the consent provided was invalid for the proposed follow-up. The Group was assured that re-consenting was not feasible due to the size of the retrospective cohort.

The CAG considered the consent that was originally provided by patients to participate in this study. Members were of the opinion that the proposed data linkage was covered by the consent which patient initially provided for their participation in the study. The Group discussed this case further and whilst it was acknowledged that a precedent set review criterion was established specifically to address validity of consent issues, so support would be recommended for this application, Members were not certain that the historic consent was always insufficient in applications which were submitted for review under this category.

It was identified that a significant number of applications which are reviewed within this category involved NHS Digital as the data controller which had confirmed that the consent was not valid for data linkage. It was agreed that the Chair would make contact with NHS Digital to discuss this issue, as it was identified

that the application in discussion represented an edge case, which the CAG had agreed to support due to the public interest in the activity progressing rather than because it was of the opinion that the consent was not valid.

- Use of anonymised/pseudonymised data

Members acknowledged that processing of confidential patient information was required to facilitate the linkage via NHS Digital.

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 e.g. month and year instead of full date of birth. The applicants had clarified that date of death was required in a complete format in order to fulfil pharmacovigilance requirements of the study, which state that deaths need to be reported with full information to the regulatory authorities. The CAG was assured by the additional rationale provided that the use of the items of confidential patient information requested was justified.

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 Group acknowledged that there had been limited patient and public involvement undertaken; however, all participants had provided fully informed consent to their participation in the study. No issues were raised in this area.

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 and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

It was explained that the applicants maintained contact with the study participants via newsletter. A copy of the most recent newsletter was provided for information purposes, which reminded and directed participants to the study website for further information. The applicants provided a copy of specific text which would be included within the forthcoming newsletter, which provided specific information around the follow-up of patients via record-linkage with wider datasets.

Additional Points

It was acknowledged that, whilst the application had been considered via full CAG, the application activity was suitable for review via the Precedent Set review Pathway and fell within the scope of the precedent set category seven – validity of consent. The submission proceeded to full CAG in order to prevent any delays to the applicant.

**Confidentiality Advisory Group Advice Conclusion**

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

**Specific Conditions of Support (Final)**

1. Patient Notification – the drafted text around patient follow-up through data linkage with wider NHS datasets should be included within the next newsletter circulation.
2. Favourable opinion from a Research Ethics Committee. (**Confirmed – 03/08/2011**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (**Confirmed – NHS Digital shows a reviewed reported grade of satisfactory on Version 14, 2016-17**).

### c. 18/CAG/0005 – Serosurveillance study of maternally derived anti-pertussis antibody

**Context**

Purpose of Application

This application from Public Health England sets out the purpose of medical research which aims to identify the amount of antibody which is required to be administered to pregnant women to protect infants from pertussis (whooping cough) in order to inform the maternal vaccination programme. The applicants will use dried blood spots from newborn baby dried bloodspot screening cards for the study. The study will be undertaken comparing antibody from DBS from 150 infants with pertussis that occurred during 2012 with DBS from 300 healthy controls. The project will be facilitated by using the PHE national surveillance activity that identified babies with pertussis disease and requesting laboratories storing the cards to take up to two of the dried blood spots that remain on the card for analysis. The laboratories will also be asked to provide two other cards taken at the same time to act as the healthy controls. The antibody test which was developed at Public Health England will be used to measure antibody concentrations to work out how much antibody is needed to protect babies from pertussis.

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

Confidential Patient Information Requested

Cohort

- 150 infants under the age of three months identified by national active surveillance between 1st September 2011 and 1st September 2012, infected with pertussis.
- 300 healthy controls – gestational age and sex matched.

Data in relation to the patient cohort will be taken from the PHE national surveillance records, which were gathered during a 2012 outbreak. The information by laboratory staff to identify a control cohort blood spot for inclusion in the study:

- NHS number – used to match records to sample
- Date of birth – used to match records to sample and identify matched control cohort,
- Gestational Age at birth – identify matched control and analysis,
- Sex – used to match records to sample and identify matched control cohort,
- Ethnicity – used to match records to sample and identify matched control cohort.

**Confidentiality Advisory Group Advice**

Public Interest

The CAG was assured that the application defined a medical purpose which was within the public interest due to the potential for improvements in the maternal vaccination programme and resulting improvements in infant health.

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 seeking consent from the retrospective cohort to be included in the study would be difficult and would involve a wider disclosure of confidential patient information. The applicants had stated that seeking consent had the potential to introduce a bias into the study results due to potential impacts on case ascertainment. Members were assured that consent was not feasible in this instance and no further queries were raised.

- Use of anonymised/pseudonymised data

The CAG recognised that the use of confidential patient information was required in order to identify the relevant cohorts to be included in the study. It was acknowledged that the analysis would be undertaken on a pseudonymised dataset.

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 e.g. month and year instead of full date of birth. Members acknowledged that date of birth was required to establish the cohorts to be included in the study; however, it was unclear from the information within the application whether it was intended to include this identifier on the research database and if so, in what format. Further clarification was required from the applicant in connection to this point.

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. The applicant had specified that support would be required under the Regulations for a two year duration in order to the complete the project. Members were unclear from this request, whether it was the intention to keep the items of confidential patient information for the two year duration, as it was suggested that once the relevant bloodspot cards had been located, it would be possible to redact the confidential patient information to a less identifiable format. It was agreed that further clarification around this point was required from the applicants in order to confirm the retention period for patient identifiers in the complete format.

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.

Members considered the patient and public involvement activity which had been undertaken to date which was described as a focus group involving 35 women of childbearing age. From the information provided, it was unclear whether the focus group had been engaged around the specific research purposes, as the description of the activity appeared to focus more generally on the use of Guthrie cards for research purposes.

The Group also queried whether the demographics of the individuals who had been approached within the focus group were relevant to the study, as it was unclear whether the women were mothers. It was further commented that wider engagement with fathers of children would be beneficial, to ensure the views of both

parents were taken into account for the project. The CAG recognised that the applicants were intending to extend the focus group activity and it was agreed that exploration of these additional points and wider audience would be required. A report would be required at this time of first annual review around the additional activity which had been undertaken in this area. 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 and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

It was explained that the applicants intended to place information on the Group B Streptococcus Support charity website around the project. Members stated that as the focus for this project was pertussis, the placement of study materials on a charity website which supports a different condition did not seem appropriate as it was unclear why individuals seeking information around pertussis would visit this website. The Group accepted that it was unlikely that there would be a specific charity or support group with which to engage around pertussis; however, it was suggested that more general support networks for new parents may be more successful in targeting the relevant audience in connection with the project. It was agreed that further work would be required by the applicant in this area to find a more appropriate channel for the placement of patient notifications. It was commented that any links established with support groups for the purposes of patient notifications could also be approached to facilitate the patient and public involvement and engagement requirements as the study progressed.

Members considered the text of the notification material which had been supplied and it was commented that the document would benefit from revision in order more clearly explain that the information related to a research project which was being undertaken. It was further commented that notification materials should be project specific – the current document referenced both the pertussis and Group B Streptococcus studies and would require revision.

Additional points

The Group queried whether the Guthrie cards were still available for use in the study, as it had been stated within the application that they were due for destruction by the end of 2017. Further information around this point would be requested from the applicant.

**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. Clarify whether date of birth will be included within the research database and if so, in what format will this be retained.
2. Clarify the retention period for the confidential patient information items requested. If it is intended to retain these for the two year period, provide further rationale to support this requirement.
3. Patient notifications and dissent – further work is required in this area to address the following points:
    a. Work should be undertaken to find a more appropriate channel for patient notifications for this study. If specific support group for pertussis cannot be located, explore more generic support networks for new parents to find a suitable alternative,

b. Revise the text of the patient notification materials to make this study-specific and make it clearer that the information is around a research study.
4. Provide further information around the intended destruction of the Guthrie cards, as it was acknowledged from detail within the application that this should already have been actioned.

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

**Specific Conditions of Support (Provisional)**

1. Patient and Public Involvement and Engagement – further work should be undertaken in this area to address the following points:
   a. Undertake further activity with a wider audience to include parents, both mothers and fathers, who have an appropriate interest in the research,
   b. Specific engagement about the proposed study, rather than general discussion around the use of Guthrie cards for research purposes, should be undertaken,
   c. A report would be required at the time of first annual review around the activity which has been undertaken, together with nay feedback,
   d. 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. (**Confirmed – North East – York REC (17/YH/0323) – favourable opinion issued 12/10/2017**).
3. Confirmation from the IGT Team NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (**Confirmed - Public Health England shows a reviewed reported grade of 72% satisfactory on version 14, 2016/17**).

**d. 18/CAG/0013 – The Family Nurse Partnership**

**Context**

Purpose of Application

This application from University College London set out the purpose of medical research to evaluate how the real-world implementation of the Family Nurse Partnership varies across England. The research will complement results from the trial, by providing a more detailed assessment of whether there are particular settings in which the Family Nurse Partnership works well. To do this, we will use electronic records that are routinely collected as part of health, education, and social care services to compare outcomes for the Family Nurse Partnership participants with similar families who did not take part in the Family Nurse Partnership.

The applicants will look at outcomes for children (e.g. emergency hospital admissions for possible neglect or abuse, development at school-age, referrals to social services) and mothers (e.g. continuing education after birth, subsequent pregnancies, hospital admissions due to violence or injuries). Exploring whether the Family Nurse Partnership works better for some families (e.g. the youngest teenagers) than others will help improve targeting of resources and highlight groups in need of alternative support. Findings from the study will help policy-makers decide whether the Family Nurse Partnership should be offered to families in their local setting. Evidence generated by this study will support commissioners in providing improved services for mothers and children who could benefit most, and lead to increased efficiency through more effective targeting of resources.

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

- Mothers (aged 13-24 years) and their children born between April 2010 and March 2017.
- There will be two cohorts – those within the Family Nurse Partnership and a control cohort which was not.
- It is estimated that the total sample size will be around 1 million patients, of which approximately 25,000 will have been included in the Family Nurse Partnership.

The following data items are required for the purposes set out below:

- Name – linkage (FNP and HES and NPD)
- NHS number – linkage (FNP and HES)
- GP Registration – linkage (FNP and HES)
- Date of birth – all linkages,
- Postcode – all linkages and analysis (converted to district level for deprivation scoring),
- Sex – all linkages and analysis,
- Ethnicity – for analysis,
- Date of death – will be provided in MM/YY format for analysis.

**Confidentiality Advisory Group Advice**

Public Interest

The CAG was assured that the application defined a medical purpose through medical research, which was within the public interest as through the evaluation of the Family Nurse Partnership, evidence would be provided to commissioners that can be used to provide improved services targeted to mothers and children who would most benefit.

Scope of Support

The remit of the CAG set out in the Health Service (Control of Patient Information) Regulations 2002 applies to confidential patient information (as defined within the NHS Act 2006). This recommendation of support extended to the release of confidential patient information from NHS Digital to the Department for Education only. It was noted that it was the responsibility of the Department for Education as data controller for the National Pupil Database to ensure that a legal basis had been established to support disclosure from this dataset.

Practicable Alternatives

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

- Feasibility of consent

The CAG was assured that consent was not feasible for this proposal due to the size of the patient cohort to be included and the requirement for a wider disclosure of information to facilitate this. No further issues were raised in this area.

- Use of anonymised/pseudonymised data

The Group acknowledged that processing of confidential patient information was required in order to facilitate linkage between the various data sources. It was recognised that analysis would be undertaken on a pseudonymised dataset.

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 e.g. month and year instead of full date of birth. Members were assured that the items of confidential patient information requested were appropriate and proportionate to the proposed application activity.

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 CAG considered the activity which had been undertaken in this area and it was acknowledged that whilst the structured workshop was a positive step and feedback had been supportive, engagement with four mothers was not proportionate to the scope of the proposed study. The Group recognised that two mothers would also be included in the study steering group and it was agreed that this would be beneficial to the project as it progressed.

Members agreed that further work should be undertaken in this area to widen the scope of the patient and public involvement and engagement activity in order to gather input from a wider sample. The Group agreed that a planned overview of how activity would be increased as the project progressed was required prior to any recommendation of support being issued. The applicants would be required to provide a report back at the time of first annual review against the proposed plan for consideration by the CAG.

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 and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members considered the patient notification materials and planned communication methodology. It was noted that the information within the document focussed at the FNP cohort provided a much clearer overview of how data would be used and which organisations were involved in the project than was detailed within the notification material intended for the non-FNP cohort. The Group agreed that both cohorts should be provided with a similar level of information in relation to the study, particularly with regards to the data items to be used and the organisations involved in the study. It was agreed that the non-FNP notification document would require revision in order to provide more project-specific information.

The Group agreed that the notification materials should clearly state that patient name, as well as wider identifiers, would be used to facilitate linkage as it was acknowledged that many would consider this to be most identifiable data item being disclosed for research purposes.

The CAG noted that an opt-out mechanism had been described for patients within the non-FNP cohort; however, no details around this had been included within the notification materials. It was agreed that information contact information should be included within this notice to allow individuals to seek further information, as well as providing details of how to raise an objection.

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 the favourable ethical opinion would be required from the applicants.

Security Assurance at the Department for Education

The Group acknowledged that the Department for Education (DfE) would be acting as data processor for the project. As a non-NHS government body, the DfE did not undertake the IG Toolkit. The Confidentiality Advice Team reported that in previous projects where linkage and processing had been undertaken by the DfE, a bespoke IG assessment had been undertaken by NHS Digital to provide assurance to the CAG around the data security arrangements and similar evidence was required in this instance.

**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. Patient and Public Involvement and Engagement – further information is required to address the following points:
    a. Provide a detailed overview of plans for additional patient and public involvement and engagement activity as the project progresses,
    b. The plan should detail how the scope of activity in this area will be widened in scope to include a larger cohort.
2. Patient Notifications and Dissent – further work is required in this area to address the following points:
    a. Documentation aimed at the FNP cohort:
        i. The document should clearly state that patient name will be used for linkage,
        ii. Include additional means of communication to supplement the email addresses provided.
    b. Documentation aimed at the non-FNP cohort:
        i. Revise the document to include a similar level of information about the project, items of confidential patient information to be processed and organisations involved, as is provided within the FNP cohort document,
        ii. Clearly state that patient name will be used for linkage,
        iii. Provide details of who can be contacted for further information about the study including contact details via a number of communication methods,
        iv. Include a section which explains how a patient can raise an objection to the use of their data for the study purposes.

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

**Specific Conditions of Support (Provisional)**

1. Support extends to the release of confidential patient information from NHS Digital to the Department for Education only.
2. Patient and Public Involvement and Engagement – a report will be required at the time of first annual review around the activity which has been undertaken in this area together with any feedback. 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.

3. Favourable opinion from a Research Ethics Committee. (**Pending**).
4. Confirmation from the IGT Team NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (**Pending – confirmation of security assurance for the Department for Education. NHS Digital shows a reviewed reported grade of satisfactory on Version 14, 2016-17**).

### e. 18/CAG/0016 – Evaluating the Effect of Community Mental Health Services

**Context**

Purpose of Application

This application from the Administrative Data Research Centre at the University of Southampton sets out the purpose of medical research with an aim to explore if administrative data sources can provide reliable long-term data to study the real world experiences of people with mental health problems in England. The study aims to establish a cohort of patients who received community mental health services in England in 2006 via the Mental Health Minimum Dataset (MHMDS) and the Clinical Practice Research Datalink (CPRD).

The study aims to investigate the effect of long-periods of adverse economic conditions on the mental health of the population. This will be undertaken by linking previously collected data from various administrative sources about an established patient population. The study cohort will be established from those patients in England receiving mental health care as recorded in the MHMDS and CPRD extracts for the 2006/7 financial year. This cohort will then be followed up across a ten year period (to 2016/17 financial year extract) in order to establish a long-term picture of the mental health care services these individuals accessed, together with detail around their socio-economic status (provided by DWP data), wide patient characteristics (provided via CPRD) and mortality data. The aims to evaluate the impact the period of financial insecurity, caused by the 2008 financial crisis, has had on the lives of mental health service users.

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

Confidential Patient Information Requested

Cohort

- Participants who received community mental health services according to MHMDS and CPRD in the 2006/7 extract between the ages of 18 – 64, living in England.
- 3 sub-groups of patients will be created:
  1. Patients captured solely on the CPRD – receiving only primary care services,
  2. Patients recorded within both the CPRD and MHMDS – receiving both primary and secondary care,
  3. Patients captured solely within MHMDS – receiving community mental health services from a secondary care provider; however, it remains unclear whether these individuals are also receiving primary care mental health services.
- The sample size is unknown but it is estimated that the MHMDS will hold approximately 200,000 eligible records and CPRD 100,000; however, the crossover between the two is not known.

The data sources are:

- Mental Health Minimum Dataset (NHS Digital),
- Clinical Practice Research Datalink (NHS Digital),
- Department for Work and Pensions Administrative Dataset,
- ONS Mortality Data (NHS Digital).

The following data sources will be included in the study; however, are out of scope for the CAG consideration as they will provide aggregated data only:

- CQC Community Mental Health Service User Survey – aggregated data only
- NHS England – bed occupancy – aggregated data only
- DH Financial Mapping Data for Mental Health – aggregated 2006-12 data only

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

- Name – linkage,
- NHS number - linkage,
- Date of birth – linkage – age kept for analysis (query at death or time of care interaction),
- Date of death – analysis – in year/quarter format only,
- Cause of death – analysis,
- Postcode – linkage – kept as deprivation index for analysis
- Address – linkage,
- Government regional office – linkage and analysis,
- Sex - analysis,
- Ethnicity – analysis.

Wider clinical and demographic information will be provided by NHS Digital which will be supplemented by economic/benefits data from DWP for analysis.

**Confidentiality Advisory Group Advice**

Public Interest

The CAG was assured that the application described a medical purpose, through medical research. It was acknowledged that there was a public interest in understanding the impact of financial insecurity, caused by the 2008 financial crisis, on the lives of mental health service users.

Scope of Project

Members were unsure about the scope of the project which had been presented. The Group commented that the documentation was unclear around whether the proposal described a feasibility study to see if the proposed data linkages of administrative data sources were possible and could provide reliable long-term data about mental health service users, or whether the application was also intending to cover the evaluation of the dataset once linked. The CAG agreed that, as the scope of the proposal was unclear, it was unable to make a recommendation against the application. Clarification was required from the applicants around the scope of the project which had been presented. It was commented that, if the proposal was also intended to include an analysis of the impact of the period of financial insecurity on mental health service users, further information would be required as part of the resubmission as to how this would be carried out and the intended outcomes for the project.

Practicable Alternatives

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

- Feasibility of consent

The CAG was assured that consent was not a feasible due to the size of the retrospective patient cohort to be included in the project.

- Use of anonymised/pseudonymised data

It was acknowledged that processing of confidential patient information was required in order to facilitate the proposed study linkages. It was noted that the study analysis would be undertaken on a pseudonymised dataset.

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 e.g. month and year instead of full date of birth. The CAG acknowledged that the items of confidential patient information which had been requested were appropriate and proportionate to the proposed activity.

Data Flows

Members were content with the proposed data flows for the project – it was acknowledged that no confidential patient information would be disclosed as all linkage would be undertaken by NHS Digital.

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 Group acknowledged that the applicants had undertaken some patient and public involvement activity; however, the results of this were not yet available. It was agreed that the outcomes of this activity would need to be provided before any recommendation of support could be considered for the application activity. An overview of how any feedback from this activity would be incorporated into the project was also required. If the responses given were negative, the CAG will take this into account when considering whether support could be recommended, or whether further actions are necessary.

Members further commented that an overview of how patient and public involvement and engagement activity would be incorporated into the project as it progressed would also be required. It was acknowledged that as the project proposed the linkage of particularly sensitive datasets, ongoing public and patient involvement and engagement activity would be an important element in ensuring ongoing public interest in the activity.

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 and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Members considered the proposed patient notification mechanism for the project. It was agreed that the information which would be displayed on the ADRN website was useful; however, it was unclear how accessible this would be to the patient cohort. It was acknowledged that wider information would be displayed on the Mental Health Foundation website to promote the project and the proposed text was considered. It was recommended that a number of communication options, e.g. telephone, email, postal, were included in the patient notification materials, to ensure this was accessible to all. The Group was assured that the wider communications strategy to promote the project was sufficient; however, it was suggested this could be considered as part of the public and patient involvement and engagement activity, to explore suggestions for a wider scope.

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 CAG raised some concerns around the potential effectiveness of the project; however, it was recognised that assessment of the scientific validity of a research proposal fell within the remit of the Research Ethics Committee. Members commented that the outcome of the REC review would need to be included within the application resubmission, to enable its deliberations to be taken into account.

**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 (Summary)**

The following information should be provided to allow the CAG to continue their consideration of the application. Response should be provided in the form of a detailed covering letter addressing each of the points below, which should be supported by a revised CAG application form.

1. Scope of the project – further information is required to address the following points:
    a. Confirm whether the proposal is a feasibility study only intending to explore whether the proposed linkage is possible and can provide a long-term dataset required to facilitate analysis of mental service users experience.
    b. If the proposal is also intended to cover the evaluation of mental health service users experience, further information is required around how this proposed analysis will be undertaken, as the evaluation element is not clearly articulated in the current application.
2. Patient and Public Involvement and Engagement Activity – further information is required in this area to address the following points:
    a. The outcome of the focus group work which has been undertaken to date is required for consideration,
    b. Provide an overview of how any feedback from this activity would be incorporated into the project was also required,
    c. Provide a planned overview of how patient and public involvement and engagement activity will be incorporated into the project as it progresses,
    d. It is recommended that the patient notification mechanism is explored with patients and the public to discuss wider methods of communications to promote patient notifications.
3. Patient Notifications and Dissent – the following points should be addressed:
    a. The information materials should be revised to include wider methods of communication to the public, e.g. email, telephone, postal.
4. Provide a copy any correspondence from the REC, including the favourable ethical opinion, if available for consideration by the CAG.

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

## 7. MINUTES OF THE MEETING HELD ON 23 NOVEMBER 2017

The minutes were agreed as an accurate record of proceedings, with no amendments raised.

## 8. CAG CHAIR REPORT

The Chair's Report was received and noted by the CAG.

## 9. EDUCATION ITEMS

The Group discussed potential education items, which were recorded by the Confidentiality Advice Team for further consideration and progression by the Chair team.

## 10. ANY OTHER BUSINESS

The Confidentiality Advice Team reminded Members of the requirement to submit expense claims in a timely fashion, particularly as the financial year end approached.

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