Minutes of the meeting of the Confidentiality Advisory Group

04 November 2021 – held via Zoom

Present:

Name	Position
Dr Tony Calland MBE	CAG Chair
Dr Liliane Field	CAG member
Dr Rachel Knowles	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Harvey Marcovitch	CAG member
Ms Rose Payne	CAG member
Mr Umar Sabat	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Dr Murat Soncul	CAG alternative vice-chair

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor
Ms Caroline Watchurst	Confidentiality Advisor
Mr Paul Mills	Senior Confidentiality Advisor/Service Manager
Ms Natasha Dunkley	Head of Confidentiality Advice Service

1. Introduction, apologies and declarations of interest

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **02 September 2021** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **02 September 2021** meeting applications.

3. Revised Applications

a. 21/CAG/0150 - Biliary Atresia Registry (England and Wales)

Context

Purpose of application

This non-research application from Kings College Hospital NHS Foundation Trust (KCH) set out the purpose of creating a registry of all infants with biliary atresia (BA) in England and Wales from Jan 1999 onwards. The purpose of the registry is to monitor

the outcome of the clinical management of BA. Prior to 1999, management in the UK was decentralised. Outcome surveys had shown that only the larger centres treating more than 5 cases per year had acceptable results, so it was mandated that the care of such infants was to be centralised and managed only at three large national centres in London, Birmingham and Leeds. Since centralisation, there has been a dramatic improvement in national outcome.

This registry has been in existence since 1999 when the Department of Health mandated that a record be kept of all infants in England and Wales with BA. However, it has been operating without a legal basis under common law, and this application is therefore to provide a legal basis under common law to retain the database which has been created retrospectively, and to provide a legal basis for the data collection prospectively. NHS England are supportive of this registry being controlled by KCH moving forwards, under 's251', as there does not appear to be any current NHS Directions mandating the data collection.

Biliary atresia is a rare, potentially life-threatening, condition of newborns characterised by persisting jaundice and the development of liver fibrosis and cirrhosis. It requires early identification and prompt surgical management to try and forestall liver failure. The registry is required to continue to provide regular, consistent and transparent monitoring of the outcomes of all infants with BA, in order to continue to improve outcomes of infants and children with this disease.

Data is collected by the direct care team in individual centres, and name is removed. At the end of each year, confidential patient information including hospital ID number, date of birth, gender and NHS number, alongside a pseudo-Identifier and clinical information about each new patient treated in the centre for BA is transferred via a password-protected spreadsheet using NHS emails, to the central database (in KCH), together with a yearly record of outcome of all infants previously registered. These annual updates of patient management and outcome for previously registered children are then linked to baseline measures via the hospital ID. Data are stored on password-protected hospital server at KCH and only accessible by Mark Davenport, and a nominated deputy.

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

Confidential patient information requested

Cohort	All infants diagnosed with biliary atresia and managed in one of the three national centres, from January 1999 onwards

	Approximately 850 infants, and more prospectively.
Data sources	Medical records at the three national centres; • Kings College Hospital, London • Birmingham Women's and Children's Hospital • Leeds Children's Hospital
Identifiers required for linkage purposes (for annual follow up)	1. Hospital ID
Identifiers retained in registry	1. Hospital ID – to allow linkage 2. NHS number – as suggested by CAG in 21/CAG/0019 (to ensure future linkage is possible if required) 3. Date of Birth – to allow linkage and for analysis 4. Maternal Postcode – for analysis 5. Gender – to allow linkage and for analysis 6. Ethnicity – for analysis 7. Date of surgical (Kasai) intervention – for analysis 8. Clearance of jaundice – Primary outcome measure 9. Associated anomalies – for analysis 10. Type of BA – for analysis 11. Need for and date of transplant – for analysis 12. Date of death – for analysis
Identifiers required for analysis purposes	1. Maternal postcode (at time of childs birth) 2. Ethnicity, 3. Associated congenital anomalies, 4. Type of biliary atresia, 5. Date of surgical (Kasai) intervention 6. Date of liver transplant 7. Date of death 8. Date of birth 9. Gender
Additional information	An update of patient management and outcomes for all previously registered children is also sent annually to KCH.

	These annual outcomes will cease once a child turns 16, but their previously collected data will remain in the registry

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The Members agreed that this application had a very important medical purpose, which is strongly in the public interest. The CAG were very supportive of the activities and stated that they do not wish to hold up the applicant any further, noting that data collection has currently been paused since January 2019, whilst a legal basis under common law is established.

Scope

As part of the response to the previously deferred application, the applicant was asked to '*clearly define the non-research purposes for which the registry will be used, and ensure this is distinct from the research purpose of the sister research application to be submitted.'*

Regarding this re-submission, the applicant provided a letter of support for the BA registry from NHS E&I, which describes non-research aims include monitoring the outcomes and clinical effectiveness of the commissioned services. There are also further clarifications in the application form. CAG considers this is enough to clarify the non-research scope of support for the registry and welcomes a sister research application when the applicant is ready to submit.

Practicable alternatives

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

- Minimising flows of identifiable information

As part of the response to the previously deferred application, the applicant was asked to 'confirm if any data is sent back from Kings College Hospital to the participating centres, as is implied on the flow chart.' Regarding this re-submission, the applicant confirmed that no confidential patient information was flowing back to the participating centres. The CAG were content with the response provided.

- Feasibility of consent

For the registry to be an effective monitoring tool, the outcome of all infants must be ascertained and therefore applicants have historically not sought parental permission to register data. Regarding retrospective data collected, the applicant reasons it would be logistically impossible to retrospectively identify and confirm parental permission dating back to 1999. Some patients will have been lost to follow-up, and many children have died. Additionally regarding prospective patients, the applicant reasons that accurate assessment of outcomes requires complete acquisition of data from all the patients born with BA, which would not be achievable with a consented model.

The Committee accepted the applicant's justifications for not taking consent for the retrospective cohort, as in the previous application. As part of the response to the previously deferred application, the applicant was asked to '*provide a clear justification as to why complete ascertainment is required, in order to explain why consent is not a practicable alternative for prospective patients.'*

Part of the applicant's argument for not taking consent prospectively is to ensure complete ascertainment, and the justification provided is to ensure '*accurate and timely data'* as stated on the NHS E&I supportive letter.

The CAG found it difficult to understand why it was not possible to collect prospective data with consent, as it seemed that the number of patients would be very low per year and commented that a consented model would not be insurmountable. However, the Members also noted that, because of the very small numbers involved, it would be important for as many patients as possible to be included in the registry.

The Committee felt that the response provided by the applicant which points to accurate and timely data capture as a justification, does not appear to mandate complete ascertainment, but rather to maximise accurate data capture. In this case the CAG agreed that whilst the response provided by the applicant was a strong argument for the CAG to agree that prospective consent was not a practicable alternative, it was not sufficient justification for not applying any type of opt outs. This will be further explained below.

In summary, the committee accepted the justifications provided regarding not consenting both the retrospective cohort and prospective cohorts for the BA registry.

- Use of anonymised/pseudonymised data

Confidential patient information is required for linkage from baseline data to annual outcome data, and for accurate analysis of clinical outcomes. The CAG accept that this cannot be undertaken with pseudonymous or anonymous information.

In the deferred application, the applicant had stated that pseudonymised data fulfils all the objectives of the registry. However, the data is not pseudonymised – the only identifier removed is name, and the data flow still contains other identifiers alongside a pseudo-identifier. The applicant was asked '*As part of the re-submission, to ensure terminology surrounding the dataset retained is correct, in that this dataset is identifiable and cannot be classed as pseudonymous'.*

As part of the re-submission, the applicant has provided a response to say the terminology in the application has been updated, however the application submitted still reads incorrectly. The Confidentiality Advice Team (CAT) had queried the applicant further regarding terminology. The applicant agreed with the fact that confidential patient information is processed in query responses, therefore the scope of support is clear.

However, the Committee were not convinced that the applicant fully understands the terminology surrounding this application, such as confidential patient information, and what can be termed anonymous data, pseudonymous data or what should be classified as identifiable. The Members were of the view that this is vitally important, as this may alter how the applicant is able to describe to both participants, or patient and public involvement groups what exactly is happening with the data. Therefore, the CAG Chair considered that this might be resolved via a meeting between the Chair and the applicant. This is therefore part of further actions requested prior to final support being provided.

Justification of identifiers

Confidential patient information in the form of hospital number alone is required for linkage from baseline data to annual outcome data. The applicant states that confidential patient information is also required for accurate analysis of clinical outcomes.

As part of the deferral of the previous application, the CAG queried whether any other identifiers would be required for linkage. The applicant has confirmed as part of the re-submission that only hospital number alone is needed.

The applicant has also agreed with the CAG recommendation to collect NHS number, in order to use this for potential linkage with other datasets in the future.

As part of the deferred application, it was noted that a large amount of identifiable information is retained for analysis purposes. The applicant was asked to *'consider if any identifiers retained for analysis can be modified to a less identifiable format, and if not please provide clearer justifications for the retention of identifiers for analysis, such as mother's postcode, date of birth, date of death, and other dates required in full format.'*

As part of the re-submission, the applicant has provided justification for most data items, noting that for infants, accurate dates are extremely important for analyses. The CAG accepted the applicant's justification for retaining full dates for analysis. However, the Committee were not convinced by the arguments provided regarding not being able to reduce the postcode to something less identifiable. The applicant has stated that the full postcode is required in order to explore if there is any geographical variation in outcome. The CAG understood why full postcode initially needed to be collected, but were less clear on why this could not then be modified to calculate the distance to the nearest centre, or calculate the distance to the centre they were treated in. The applicant is therefore asked to further justify why full postcode is required for analysis, and why this cannot be modified to distance, or sector level postcode.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object 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.

The notification provided for the previously deferred application was considered not fit for purpose in the previous format. The applicant was asked to 're-develop patient

notification leaflets as described in the deferral letter. These should include separate information for older children or young adults. The applicant should make it clear where these notifications will be displayed, and ensure that a layered approach is in place, linking to a more detailed GDPR privacy notice.'

As part of the re-submission, the applicant has provided a letter informing parents of the inclusion of their child in the registry, which will be given at discharge from the initial treating hospital, in conjunction with their information package that is given on discharge. This contains contact details for objection or queries.

A letter will also be sent to teenagers and young adults informing them of the Registry and the nature of the data collected. This contains contact details for objection or queries. The sending of these letters will be undertaken by the direct care team at each Trust.

Details of the Registry will be displayed on The Children's Liver Disease Foundation website, also giving contact details for objection or queries. A link to GDPR style privacy notice has also been added into these letters as a response to CAT queries, however this privacy notice is the generic KCL information and is not specific to the registry.

The Members considered these letters to both parents and children as not adequate for purpose. It was noted that the patient notification for this registry should accurately reflect the processing of confidential patient information without consent, and outside the direct care team, in order for both the parents and any children aged either below 16, or especially those over 16, to fully understand the details of the registry, in order for them to be able to opt out if they wish to. The CAG commented that access to patient information without consent is a privilege, not a right, and in the case of this registry, having agreed to recommend 's251' support for a prospective data collection (rather than consent), it is imperative that the notification provided is good enough, and a robust opt out process is in place. The members also noted that the notification materials had not been reviewed by a patient and public involvement group as suggested.

As explained in the previous deferral letter, the patient notification should state which data items are collected and how, (including the annual follow up data disclosure, and the data flow between Trusts). The legal basis of the data collection and processing also needs to be explained. It was also noted that it should be made especially clear to parents that the mother's postcode at the time of their child's birth will be collected and retained for analysis indefinitely. There are incorrect statements regarding the function of CAG which are required to be corrected; *'The contents and design of the Registry have been approved by the Confidentiality Advisory Group'* should be altered to state something similar to the following; 'The Secretary of State for Health and Social Care, following advice from the Confidentiality Advisory Group (CAG), has provided support for the Biliary Atresia Registry to process confidential patient information without consent under Regulation 5 of the Health Service (Control of Patient Information)

Regulations 2002 ('section 251 support').' The notification should also clearly explain why the data is collected.

The Members noted that the letter designed for older children was not particularly different to that for adults, and it was not felt this was a very suitable document to use as a notification for children turning 16. The process was also not described very clearly, apart from the applicant confirming the direct care team in each trust would be sending the letters.

It was felt very strongly by Members that there needed to be a very good patient notification available for children included in the registry at the point they were turning 16, to ensure there is a method of patient notification as they become adults.

Therefore, these notification materials need to be further developed on the basis of the advice above, and the applicant should think about other ways of informing the cohort, for example posters in clinical areas in each Trust. The newly developed notification materials should be reviewed by a patient and public involvement group, as suggested in the previous deferral letter.

As part of the previous deferral, it was proposed that '*the applicant should develop an opt out method, including how to implement the national data opt out, or provide a strong justification for not implementing an opt out option.'*

The applicant has not provided a clear justification for not implanting either a study specific opt out or the national data opt out. The applicant agreed in responses to CAT queries that an opt out option could be provided specifically for the registry on the notification letters. Therefore, the CAG were content that a dissent mechanism would be offered. However, in order for study specific opt out options to work effectively, the information provided on the notifications need to be very accurate, and therefore the above information is extremely important to take on board.

As this is a very rare patient group with less than 1000 patients over 20 years, the CAG were happy to waive the need to apply the national data opt out, but only in the context of having a very robust study specific option to opt out.

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 the unconsented activity should go ahead.

As part of the deferred application, '*further Patient and Public Involvement and Engagement is required to be undertaken as part of a re-submission, specifically requesting feedback on*;

a) *The acceptability of this use of the confidential patient information without consent;*
b) *Their opinions on the level of confidential patient information retained;*
c) *Feedback surrounding newly developed notification materials;*
d) *Opinions on whether an opt out should be offered.'*

As a response to deferral, the applicant has circulated a questionnaire to 12 sets of parents of newly diagnosed patients with BA inquiring about attitudes to consented and unconsented data collection, storage of data and provision of follow-up data. 6 sets of parents returned the forms. All but one of the returned forms supported the use and collection of unconsented data. They were less clear of the need to prolong follow-up and data collection beyond adolescence, and therefore the applicants will not continue to follow-up young people into adulthood beyond their 16th birthday. The applicant has not asked any patient and public involvement group about newly developed notification materials. The questionnaire states on it; *The data is always stored without personal details such as name and address to ensure that your child could not be personally identified (described as "anonymised" or "pseudoanonymised").* However, listed as data items are hospital number, ethnicity and date of birth as retained in the dataset. NHS number is not mentioned, and nor is postcode. CAG were therefore unsure if applicant has met a), but probably the parents did understand that the data items listed were recorded without consent, and supported this. b), applicant does not appear to have asked. c) applicant has not asked. d) applicant has met this element, and an opt out option has now been included.

The CAG consider that more patient and public involvement is required to be undertaken, which properly describes the use of confidential patient information without consent to patient and public involvement participants, instead of referring to anonymised or pseudonymised information. The CAG noted that one parent felt consent should be required. The Members felt more information should be provided to people in order to describe why it is an important data collection. The CAG felt very strongly that there must be some more engagement with patients and the public to explain exactly what is going on and explain why this is in the public interest.

It was also felt that some children should be consulted with if possible. The Members wondered if KCL had access to a patient and public involvement group that the applicant could seek help from?

As part of the previous deferral letter, '*The applicant should consider creating a steering committee for the registry which includes lay representation.'* The applicant has stated as part of the resubmission that he is in negotiation with the CLDF about

aspects of the registry going forward and will invite lay representation on a future steering committee. The CAG welcomed this update and requested further details on the structure of the steering committee, which would include lay representation.

Exit strategy

Support was requested for an ongoing registry – Biliary atresia patients are never cured of their disease and require life-long out-patient based care often in the centre that originally treated them. There is a continual need for liver transplantation in these patients even if they reach early adulthood. Members were content with the exit strategy described, as this is in line with other national registries. However, at the point support is provided, this is usually given for an initial period of five years and would also be subject to submitting an annual review each year.

When children reach 16 years old, the applicant plans to cease annual follow up. Their previously collected data will remain in the registry.

Independent audit

As part of the deferred application, the applicant was asked to explain '*if this audit is the mandated independent audit, and if so, please describe how it fulfils this purpose. Consider providing more relevant up to date evidence regarding the mandated audit.'* And was also asked to '*provide as part of a re-submission, the document from 1999 which mandates KCL to establish the registry and details what the registry should cover.'.*

As part of the re-submission, the applicant does not have any evidence from 1999 that mandates KCL as the 'independent' audit. However, the applicant has provided a supportive letter dated April 2021, from NHS E&I regarding the registry, and it does not appear there is a requirement for this to be carried out independently of the applicant at KCL. The Chair considers 's251' support is required for this registry. The Members were agreed that there does not appear to be a mandate for this data collection, but also noted that this is in modern terms. In 1999, which predated Section 60, and any data protection legislation, it is perfectly possible at the time that the terminology 'mandatory data collection' could have been used. The Chair can further explain this history if required in the communications he will have with the applicant.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Secretary of State for Health and Social Care that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

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

Request for further information

1. Please arrange a meeting with the CAG Chair (Via CAT). This is to ensure the applicants understanding of terminology and other important elements of this application.

2. Please provide further justification regarding why full postcode is required for analysis, and why this cannot be modified to a less identifiable format.

3. Please provide updated patient notification for both parents and children turning 16, as described above. These notification materials should include;

    a) The data items collected
    b) How the data is collected (including the annual follow up data disclosure, and the data flow between Trusts),
    c) The legal basis of the data collection and processing.
    d) It should be clear that the mothers postcode will be collected and retained for analysis indefinitely.
    e) Correct the statements regarding the function of CAG which are required to be corrected; *'The contents and design of the Registry have been approved by the Confidentiality Advisory Group'* should be altered to state something similar to the following; 'The Secretary of State for Health and Social Care, following advice from the Confidentiality Advisory Group (CAG), has provided support for the Biliary Atresia Registry to process confidential patient information without consent under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support').'
    f) Clearly explain why the data is collected.
    g) Ensure the notification for those turning 16 is age appropriate (and describe the process of how they will be notified)
    h) Consider developing a poster for clinical areas

i) Ensure the above documents are discussed with a patient and public involvement group.

4. Further Patient and Public Involvement and Engagement is required to be undertaken. This should better describe the activities, and not refer to the information being processed as anonymous or pseudonymous. Children should be asked for their opinions if possible. Feedback should be specifically requested on;

   a) The acceptability of this use of confidential patient information without consent;
   b) Their opinions on the level of confidential patient information retained;
   c) Feedback surrounding newly developed notification materials;

5. Please provide further details on the structure of the steering committee, which would include lay representation.

Once received, 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, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Support will be provided for 5 years in the first instance. A duration amendment will be required at this time to ensure continuing ‘s251’ support.

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information. **Confirmed:**

   The NHS Digital **20/21** DSPT reviews for **King’s College Hospital NHS Foundation Trust** and **Birmingham Women's and Children's NHS Foundation**

Trust and **Leeds Teaching Hospitals NHS Trust** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 25 November 2021).

b. 21/CAG/0160 - Secondary/additional findings in 100,000 Genomes Project evaluation

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research that seeks to develop understanding of the correlation of specific additional findings (AF) with clinical and family history relevant to health condition associated with AF, and clinical follow up and clinical outcomes relating to specific AF following disclosure.

Whole genome sequencing (WGS) is a powerful, recently developed technology that allows the simultaneous analysis of vast amounts of genetic information, with the potential to define and understand the genetic changes that have lead to disease development. In the Genomics England 100,000 Genomes Project, the primary use of WGS was to identify the precise genetic changes associated with currently manifested disease. It is also possible that WGS could be used to identify genetic changes that may be associated with risk of future disease development or unexpected disease. Such variants have been termed "secondary" or "additional" findings, and it is currently unclear how such information should be managed. Analysis of the benefit and harms of WGS needed to be carried out in order to information discussions on whether genome variants that may identify pre-disposure to future or asymptomatic disease should be disclosed to patients and/or participants.

NHS England has established several Genomic Medicine Service Alliances (GMSA) to deliver genomic medicine in the NHS, including legacy activities of the 100,000 Genome Project, such as reporting of AF to the patient participants. This study will focus on patients in the South Central GMSA, which covers the West Midlands, Oxford and Wessex, and represents around one fifth of participants recruited. The trusts included in the South Central GMSA are Oxford University Hospitals NHS Foundation Trust, Birmingham Women's and Children's Hospitals NHS Foundation Trust, University Hospitals Birmingham, University Hospitals Southampton Hospitals NHS Foundation Trust. Confidential patient information is collected by clinical personnel and stored in patient records as part of clinical care. The SAFE study team, up to 3 researchers who

are not members of the direct care team, will access this information for 12 months after disclosure. The information will be collected either remotely or by visiting trusts, if remote access is not possible. The researchers will enter the required information onto a CRF. Patients will be identified by a study code only, so that the information will be pseudonymised for research storage and processing. The pseudonymised information will be stored on a database held securely by the University of Oxford.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	400 patients recruited to the 100,000 Genome Project within the South-Central Genomic Medicine Service Alliances (GMSA) and who were informed by the NHS that they have an AF in their sample.
Data sources	1. South Central Genomic Medicine Service Alliances, which is comprised of the following NHS Trusts: a. Oxford University Hospitals NHS Foundation Trust b. Birmingham Women's and Children's Hospitals NHS Foundation Trust c. University Hospitals Birmingham NHS Foundation Trust d. University Hospitals Southampton Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID number 4. Date of birth 5. Date of death

	6. Postcode – district level
Identifiers required for analysis purposes	1. Postcode – sector level 2. Gender 3. Ethnicity

Confidentiality Advisory Group advice
The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest
The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was in the public interest.

- Feasibility of consent

The applicants advised that a comprehensive dataset is required to understand the issues under investigation, and noted that seeking consent may risk attrition rates, limiting the research.

The applicant also noted that the clinical consultations, where patients will be informed of their AF, will involve discussions of the risk of a potentially new serious health condition affecting the patient and their relatives. In many cases, such consultations will be complex and anxiety- inducing for the patient and the health professional. It would be impracticable to seek consent from patients during these consultations. The study also involves collecting data at multiple points, from several clinical specialties, and it would not be practicable for the clinical care teams to extract all required data.

The applicants explained that participants took part in the 100,000 Genomes Project in order that a genetic cause could be sought for their manifest disease, a rare disease or cancer. Participants were either personally affected, or were recruited as a healthy parent of an affected child. At the time of recruitment through the NHS, participants were offered the choice to receive 'additional findings' (AFs): these are genomic findings unrelated to the original health condition. AFs are associated with risk of serious disease, cancer predisposition or familial hypercholesterolemia.

There is no precedent in clinical practice for returning genomic information associated with serious disease 'out of the blue'; predictive genetic testing has always been offered with pre-test counselling, so that patients understand the test purpose and implications, and are psychologically prepared for the result. The study team has been researching in this area for several years and has returned a very small number of AFs on a research basis. The applicants had found that recipients experience a range of emotions including distress, anxiety and fear, and take time to process the information. AFs relate to diverse diseases and there is no single clinic in which patients will be managed. In clinical appointments to disclose and discuss the finding, patients may be learning a serious health risk for the first time and are likely to experience strong emotions; consultations may be long and complex.

The applicants noted that recruitment materials could be mailed to participants, but from previous experience of clinical research, this would result in loss of significant numbers of patients which would compromise the research.

The CAG agreed that it was not feasible to seek consent.

- Use of anonymised/pseudonymised data

Patients date of birth and date of death will be converted to age and age at death, prior to information being removed from the sites. The CAG raised no queries in this area.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient

information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object 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.

The applicants provided a Privacy Notice. This included information on how patients can dissent and a link to information about the GDPR on the University of Oxford website. An email address was provided for the University's Data Protection Officer, Clinical Trials and Research Governance at the University of Oxford and the Chief Investigator. The applicants advised that they had enquired about including this on the 100,000 Genomes Project website but were advised that this was not possible. Genomics England had agreed that social media can be used to publicise a link to the Oxford University website, where the Privacy Notice will be posted when all required approvals are in place.

In response to the previous, Deferred Outcome, the applicants provided a separate Patient Notification document. This had been created in consultation with the Chair of the 100,000 Genomes Project Participant Panel. The notification explained what additional findings are. Telephone numbers were provided for patients to contact the researchers with queries or to opt-out. A website address will also be included, although the address is not included at the moment, via which patients can opt-out. Patients are asked to provide their NHS number when opting-out via the website or phone.

The applicants had discussed the issue of patient notification with the 100,000 Genomes Project participant panel Chair, in person and by email. The Chair shared the applicants' concern that consenting patients during their clinical consultation would be intrusive given the potential worry incurred by the AF. However the Chair felt that using social media alone to publicise the patient notification document would not be adequate. The applicants and Chair agreed on the approach of mailing the patient notification document as a leaflet with the post-clinic letter. Researchers and the panel Chair then co-wrote the patient notification document, and discussed how to ensure that patients see it and are able to opt out in a convenient manner. The approach agreed was to send the patient notification document as a leaflet with their post-clinic letter, and to offer a means of opt out that would not involve interaction with an individual researcher.

A Patient Information Leaflet was also provided, intended for patients who are invited to the interview stage, which is outside the scope of this application.

The CAG considered whether it was reasonable for the applicants to ask those wishing to opt-out to provide their NHS number, noting that they may not know their NHS number. Members noted that patients would have previously received a clinic letter, which would contain the NHS number, and agreed that this should be sufficient.

The CAG agreed that the Privacy Notice needed to be clearer and suggested it was revised. Members noted that this was a recommendation rather than a requirement.

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 the unconsented activity should go ahead.

The Chair of the Genomics England 100,000 Genomes Project Participant Panel has agreed to join a study management committee. The applicants also presented the study to a Southampton based PPI group in June 2021.

The 100KGP participant panel is made up of participants from the 100,000 Genomes Project, and parents or carers of people involved in this project throughout the UK. A meeting was convened between the PI and Chair of the panel, in May 2021. Following this meeting, the 100KGP participant panel Chair was asked, and agreed, to sit on a SAFE steering group.

A summary of SAFE was drafted, which the Chair shared with the 100KGP participant panel and sought their views. The Panel was comprised of 23 people. 3 responded, who were all broadly supportive but had further questions. One panel member sought further clarification of the overall objectives and intended outcome of the study. Minor changes to the interview guide were suggested.

When preparing their response to the Deferred Outcome, the applicants had further discussions with the 100,000 Genomes Project participant panel Chair, in person and

by email. The Chair expressed concern that consenting patients during their clinical consultation would be intrusive given the potential worry incurred by the AF. However the Chair felt that using social media alone to publicise the patient notification document would not be adequate. The applicants and Chair agreed on the approach of mailing the patient notification document as a leaflet with the post-clinic letter. Researchers and the panel Chair then co-wrote the patient notification document, and discussed how to ensure that patients see it and are able to opt out in a convenient manner. The approach agreed was to send the patient notification document as a leaflet with their post-clinic letter, and to offer a simple means of opt out that would not involve interaction with an individual researcher. The applicants will continue to liaise with the 100,000 Genomes Project Participant panel. In addition, a Patient Participant Voice panel is being established for Genomic Medicine Service Alliances.

The PI also attended a separate University Hospital Southampton NHS Foundation Trust Patient and Public Involvement Team coffee morning which generated a general discussion of patient data in research. The applicants will ensure that ongoing dialogue between SAFE researchers and the 100KGP participant panel takes place, via the Chair, sharing progress and inviting input.

The CAG noted that the patient and public involvement carried out was conducted with a small group and with the 100KGP participant panel Chair. The CAG asked that further patient and public involvement was undertaken with a wider group and reported back to the CAG at the first annual review.

Exit strategy

The applicants advised that patients' date of birth and date of death will be converted to age and age at death, prior to information being removed from the sites. The CAG raised no queries under this heading.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Further patient and public involvement is to be undertaken and reported back to the CAG at the first annual review.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 19 August 2021.**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS Digital **2020/21** DSPT reviews for Oxford University Hospitals NHS Foundation Trust, Birmingham Women's and Children's Hospitals NHS Foundation Trust, University Hospitals Birmingham NHS Foundation Trust and University Hospitals Southampton Hospitals NHS Foundation Trust, were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 04 November 2021)

4. New applications

a. 21/CAG/0148 - Postoperative vasopressor usage: a prospective observational study. Relation to Perioperative Atrial Fibrillation (AF)

Context

Purpose of application

This application from the University of Liverpool set out the purpose of medical research that seeks to identify the proportion of patients who develop post-operative atrial fibrillation.

Some patients develop a syndrome called vasoplegia while undergoing surgery. Vasoplegia occurs when the function of blood vessels become impaired, blood pressure falls to abnormally low levels and additional medications (vasopressors) are required to maintain blood pressure. If vasoplegia persists after surgery, it often necessitates

admission to the intensive care unit for management of vasopressors, which results in prolonged hospital stays and a greater risk of complications, including the development of atrial fibrillation (AF), an irregular heart rhythm that increases the risk of stroke and death.

The applicants seek to investigate the prevalence of post-operative AF in a non-cardiac surgical population. The study will be conducted in two parts and two cohorts will be involved. The SQUEEZE UK study will be conducted in at least 40 UK centres and the data collected in this study will be analysed as part of a worldwide study to understand the impact of vasoplegia on outcomes.

In the first part, cohort A, data will be collected from all patients who undergo surgery as hospital inpatients in order to determine the proportion who develop vasoplegia and AF, and to identify any risk factors. Suitable patients in cohort A will be identified by members of the direct care team (the perioperative anaesthetist). The clinical research team will then access confidential patient information in patient records to extract a pseudonymised dataset onto CRF 1. Additional information for patients will receive a Post-operative Vasopressor Infusion (PVI) will be collected and entered onto CRF 2. Information for patients who develop AF will be collected and entered onto CRF 3.

In phase two, cohort B, 30 patients recruited into cohort A from each participating centre who develop vasoplegia will be followed up in detail. Patients in cohort B will be identified by the clinical research team, who will then access confidential patient information in patient records to extract a pseudonymised dataset.

Support is required as, while the applicants expect that members of the direct care team will undertake processing of confidential patient information to identify patients for cohort A within some of the participating trusts, this would not be the case in all trusts. The applicants noted that one week of heavy workload would be involved, meaning that research nurses may need to process confidential patient information to recruit cohort A. A pseudonymised dataset will be extracted and entered onto the Clinical Report Forms (CRFs). The pseudonymisation key will be held by the participating trusts and Health Boards. Any re-identification of patients required will be undertaken by the Trust had submitted the information, who will retain the pseudonymisation key. The information uploaded to the ESAIC will be effectively anonymised. The anonymised dataset will be sent to University College London for analysis.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Cohort A: Patients aged 18 years and over at the time of surgery, who have undergone surgery and were not discharged on the day of surgery. Cohort B: Patients aged 18 years and over at the time of surgery, who have undergone surgery and were not discharged on the day of surgery, and who received an infusion of vasopressors which continues after the patient has left the operating room. 5000 patients will be included in England and Wales.
Data sources	2. Electronic patient records at 51 participating NHS Trusts and Health Boards in England and Wales.
Identifiers required for linkage purposes	7. NHS number 8. Date of birth
Identifiers required for analysis purposes	4. Date of birth 5. Date of death 6. Gender 7. Study number (patient identification number)

Confidentiality Advisory Group advice
The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was in the public interest.

Practicable alternatives

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

- Processing of confidential patient information by the direct care team

The applicants had advised that participating trusts that have a DSPT that has been reviewed by NHS Digital and found to have met their standards will come under the scope of support under Regulation 5. Trusts that have not met NHS Digital DSPT standards will only be able to take part if confidential patient information is processed by the direct care team only.

- Feasibility of consent

The application includes some inconsistencies over the reasons for not seeking consent and the protocol refers to a consent process.

The applicants have clarified that the two main reasons for not seeking consent from patients are to avoid introducing bias by omitting patients undergoing emergency surgery who may be most likely to develop complications. Also, recruitment for Cohort A will be conducted over one week and each site will need to recruit approximately 100 patients during this week. It would not be feasible for research nurses to under the consent process under these time constraints.

The CAG agreed that consent was not feasible.

- Use of anonymised/pseudonymised data

Only pseudonymised information will be extracted onto the CRFs and anonymised information only transferred outside of participating centres. The CAG raised no queries under this heading.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object 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.

A poster had been provided (Squeeze UK Poster_v1). This gave brief information about the study, but did not explicitly state that patients' hospital records would be accessed. It also doesn't explain that patients can dissent. The applicants advise in their response to the CAT Advice Form that telephone, email and postal contacts will be provided, however only telephone, email and website contacts were included on the poster.

Contact details will be provided for the local Principal Investigator and study co-ordinator. The SQUEEZE UK website address and an email address for the SQUEEZE UK research team will also be included.

The posters will be displayed in preoperative clinics, recovery areas and within theatres to inform patients about this study. Handouts of the poster will be available in waiting areas for patients to take home if they wish. If preoperative assessments were conducted online, the link to the project webpage would be provided.

The CAG noted that the information on the poster was very brief. Members agreed that more information needed to be given, including an explanation that patient hospital records will be looked at and that patients can dissent to the use of their information. A brief explanation of the opt-out process also needed to be included.

Information would also be made available about the study on a study website. Members asked that a link to this information was included on the poster. The text of the website information also needed to be provided to the CAG for review.

The CAG asked the applicant to advise how long prior to the data extraction the posters would be on display. Members noted that a four to six week lead-in period was usually recommended.

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 the unconsented activity should go ahead.

The applicants advised that they had engaged with patients and the public to explore potential concerns about the research, to learn about patients' interest and priorities for research in perioperative atrial fibrillation (POAF) and to understand the relevance complications of POAF such as stroke may have for patients and the public.

The proposal was presented to two Patient and Public Involvement Panels (PIP) at the University of Liverpool and has been discussed with the Liverpool Heart and Chest Hospital's Research Patient Ambassador. The founder and CEO of Arrhythmia Alliance has also been instrumental in shaping the design of the research agenda and protocol.

Two charities, Arrhythmia Alliance and AF Association also support the project and will help to distribute results and news about the project via newsletters and emails. Arrythmia Alliance and AF Association also organise sessions at major international meetings and conferences to represent patients' experience and views. The applicants will feed into this activity by presenting at such meetings and engaging with all stakeholders.

The applicants have discussed with the Liverpool Heart and Chest Hospital's Research Patient Ambassador and the founder and CEO of Arrhythmia Alliance the best ways to obtain patient views on processing confidential patient information without consent. Following this discussion, the applicants decided to hand out the patient information leaflet to patients having undergone emergency surgery postoperatively at a time point when patients are well enough to weigh and retain the information provided.

The CAG noted that it was unclear whether patient and public involvement had been undertaken specifically around the use of confidential patient information without consent. Members agreed that feedback from patient and public involvement discussions that specifically include the use of confidential patient information without consent needed to be provided.

Exit strategy

A pseudonymised dataset will be extracted and entered onto the Clinical Report Forms (CRFs). The pseudonymisation key will be held by the participating NHS Trusts and Health Boards.

In their initial responses to the CAT Advice Form, the applicants had advised that support was required as the pseudonymised dataset could possibly contain information that would render patients potentially identifiable. They then clarified that the local

centres will retain the pseudonymisation key and that the information uploaded to ESAIC will be effectively anonymised.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

Request for further information

1. The study poster needs to be revised as follows:
    a. Further details needed to be given on the poster, including an explanation that patient hospital records will be looked at.
    b. It needs to be clearly stated that patients can dissent to the use of their information and a brief explanation of the opt-out process also needs to be included.
    c. A link to the website information needs to be included.

2. The text of the website information needs to be provided to the CAG for review.

3. Feedback from patient and public involvement discussions that specifically include the use of confidential patient information without consent need to be provided.

4. Advise how long prior to the data extraction the posters will be on display.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed: Favourable Opinion issued 16 September 2021.**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Not checked due to the number of sites involved in the study. Support is recommended on the basis that it is the**

applicant's responsibility to ensure that the required security assurance standards have been met at each site prior to processing any confidential patient information with support under the Regulations.

b. 21/CAG/0155 - Using patient records to identify potential participants for the fourth National Survey of Sexual Attitudes and Lifestyles (Natsal-4)

Context

Purpose of application

This application from the University College London set out the purpose of medical research that seeks to use confidential patient information held by NHS Digital, to create a sampling frame in order to invite English participants to consent into the fourth National Survey of Sexual Attitudes and Lifestyles (Natsal-4). Natsal is the world's largest, most detailed study of sexual behaviour, and has taken place every 10 years (1990, 2000, 2010). Previous iterations have used an address-based sample frame (Postcode Address File - PAF), and conducting eligibility screening and selection on the doorstep. However this has been found to be inefficient, especially regarding young person and ethnic minority boost samples, who experience a disproportionate burden of adverse sexual and reproductive health outcomes. The applicants plan to use name based sampling for the 'dress rehearsal and mainstage' of Natsal-4, but will also include the address based sampling into their ethics application as a back-up in case they cannot implement the names based method in time. However they do not consider this to be a practicable alternative to CAG support, due to the huge inefficiencies found in implementation, and the lack of ability to include boost samples.

Natsal-4 will provide updated nationally representative data on sexual and reproductive health. Past equivalent data has been extensively used to guide policy and practice, including to improve sexual health education, design interventions (e.g. chlamydia screening, teenage pregnancy strategy, HPV vaccination) and deliver health services.

The Natsal research team at NatCen provide NHS Digital with a specification of the sample file requirements. This will provide the number of records required, the geographical areas to be included, and the stratification requirements (e.g. by age, ethnicity, and potentially other demographic stratifiers). NHS Digital will create a named sampling frame from Demographics and HES datasets, and provide this information to NatCen. NatCen will disclose this information on to Formara, and also to individual interviewers in order for them to consent patients as part of fieldwork. Natsal-4 aims to

achieve a consented sample of 10,000 participants aged 16-59 who will be randomly selected from across Britain. Applicants plan to include young person (16-29 year olds) and ethnic minority boost samples to ensure robust subgroup analyses in these groups. Prior to the letters being sent, the applicants plan to have a notification on the study website, so people can opt out of this if they wish.

Formara send out invitation letters to patients, which also have an opt out option included on the letter. Approximately a week later, an interviewer will visit the address of the selected individual and will explain the study further. This is the same approach used in a number of other social surveys (including the Mental Health of Children and Young People 16/CAG/0016). The patient is then consented into the study, and asked to complete a computer-assisted questionnaire, provide a biological sample (urine or vaginal swabs) and consent to data linkage, and these elements are therefore out of scope for support as they are undertaken with consent as the legal basis under common law.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Participants aged 16-59 resident in private households in England. Up to 80,000 will be approached via letter in order to consent 10,000.

	Boost samples of young people (16-29) and ethnic minorities will also be recruited, this is included in the above figures.
Data sources	1. NHS Digital: a. Demographics b. Hospital Episode Statistics (HES)
Identifiers required for linkage purposes	9. Full name 10. Address including postcode 11. Gender 12. Date of birth 13. Ethnicity
Identifiers required for analysis purposes	8. N/A any data for analysis is retained with consent

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The Members agreed that this activity was strongly in the public interest.

Practicable alternatives

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

- Feasibility of consent

The applicant reasons that the statistical theory underlying probability sampling methods requires that each member of the target population has a known, non-zero chance of selection. It is not feasible to obtain consent from all individuals who are eligible to participate in Natsal, as it would involve seeking consent from all 16-59 year-olds in Britain. Instead, applicants are seeking 's251 support' in order to approach people to invite them to participate in the Natsal study. Fully informed consent to participate in the research study will be obtained from participants prior to any study data collection. The CAG agreed with the justification provided.

- Use of anonymised/pseudonymised data

Confidential patient information is required to identify patients in order to gain consent. It is not possible to invite patients to participate without their name and address, other than the previous method of random address sampling, which the applicants reason is inefficient and not possible to identify boost samples. The Members were content with the reasoning provided.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object 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.

As in previous Natsal surveys, selected individuals will be sent an advance letter and leaflet informing them that they will be visited at home by a trained survey interviewer from NatCen Social Research (NatCen). This advance mailing will contain information on the study and its importance, what taking part involves and who to contact for further information. The letter also explains that participants can let NatCen know if they don't

want an interviewer to visit their home and provides a freephone number to enable opt-outs, however this is after the breach has occurred.

As a response to queries, applicants have developed a notification to display on the study website prior to the breach to enable people to opt out of being sent a letter. They have reasoned that it is almost impossible to target all 16-59 year olds in England with a communication strategy.

An opt out option prior to the breach has been developed. There is also an opt out option on the invitation letter, and an opt out option on the doorstep. The National data opt out will be applied by NHS Digital.

The poster/leaflet provided will update the section '*how did you choose my address'*, to explain the new sampling method, and to state that HRA has 'given permission' for this to be undertaken. It is noted by the members that this terminology Is not quite correct, and this should be amended to reflect the advisory nature of the CAG. For example; '*the Study has received Favourable opinion from an HRA REC, and the Health Research Authority, on advice from the Confidentiality Advisory Group, has recommended support under 's251' in order to process confidential patient information without consent.*

It was noted by the Members that there was only a phone number provided on the initial invitation letter to register an objection. The CAG considered that an email address and a postal address should also be provided in order for people to opt out.

The Committee also noted that it appeared the researchers would undertake home visits one week after the initial invitation letters had been sent. The CAG did not consider the time period to be long enough, and have asked for further justification if this time period cannot be extended.

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 the unconsented activity should go ahead.

Natsal is a study representing the general population (rather than a particular group of patients or service users). The applicants have undertaken a large amount of patient and public involvement with different stakeholders surrounding question content. Applicants have provided information around application 16/CAG/0016 being conducted on 18,000 records, and only receiving 2 complaints as evidence of a similar level of acceptability to obtaining the Natsal named sample, especially as both surveys cover sensitive topics. Applicants have also discussed the new study design with the interviewers, who have undertaken this type of survey work before using named samples.

As a response to queries regarding the acceptability of the use of confidential patient information without consent in the design suggested, the applicants have devised some questions which they will ask a group of stakeholders and interested members of the public, who attended a consultation between June and July 2019 about views on the development of Natsal-4. This is planned for the future, and has not yet been undertaken.

CAG considered that some patient and public involvement should be undertaken before the study begins. The CAG also considered the questions devised by the applicants need to be more specific regarding the disclosures of confidential patient information. The applicants would need to describe the data flow more clearly, including what data is disclosed, where it would go, and who would see it, so that the patient and public involvement representatives can make informed comments on the acceptability of the breach occurring.

Exit strategy

Upon completion of processing activities, Formara will securely destroy the mailmerge file. This will be undertaken by November 2023. Some personal data (name, address, contact details) will be recorded on paper documents by interviewers so that they can arrange the interview. They will be securely destroyed (shredded) at the end of the fieldwork assignment.) Upon completion of each fieldwork assignment, sample information is securely deleted from interviewer laptops and paper documents containing personal data are shredded. Fieldwork will be conducted over 18 months between July 2022 and December 2023. Fieldwork will be issued over a series of 9 waves. Confidential patient information disclosed to NatCen will be deleted at a time

point no later than by 01 October 2024. Support therefore required until 1 October 2024. The CAG were content with this exit strategy.

Protocol

It is noted that there is currently no protocol that covers the study including the new sampling method. An updated protocol should be provided when available.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Please provide an updated notification poster/leaflet, with the specified changes regarding the HRA 'giving permission', and ensure that the version provided to CAG has been edited to reflect the correct sampling method.

2. Please update the initial invitation letter with additional opt out contact details to include telephone, email and postal.

3. Please clarify if the length of time between initial invitation letter, and interviewer arriving on the doorstep can be extended to longer than one week? If not, please provide justification.

4. Please develop further descriptions/questions surrounding specific processing of confidential patient information without consent, naming organisations and describing data flows and items, in order to present to a patient and public

involvement group. The CAG will also want to see evidence of some responses prior to recommending support.

5. Please provide an updated protocol which includes the study design presented to CAG.

6. It is understood that the applicant has agreed with REC to submit the Natsal-4 mainstage (which cover the elements relating to CAG application) as an amendment to IRAS reference 275649. This is awaiting favourable opinion. Please provide to CAG when available, as per standard condition of support below.

7. Please provide evidence of NHS Digital review of 20/21 DSPTs for NatCen social research and Formara Limited, as per standard condition of support below.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee **(regarding amendment) Pending**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Pending:**

   The NHS Digital **20/21** DSPT review for **NHS Digital** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 23 November 2021).

   The NHS Digital **20/21** DSPT reviews for **NatCen social research** (8HW76) and **Formara Limited** (8JK40) are pending.

5. Minutes of the meeting held on 30 September 2021

The minutes of the meeting held on 30 September 2021 were not reviewed as an outcome is pending.

6. Any other business

No other business was raised.

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

Signed – Chair	Date

Signed – Confidentiality Advice Team	Date