Minutes of the meeting of the Confidentiality Advisory Group

15 April 2021 at Meeting via Teleconference

Present:

Name	
Dr Martin Andrew	CAG Expert Member
Dr William Bernal	CAG Alternative Vice-Chair
Dr Malcolm Booth	CAG Expert Member
Ms Sophie Brannan	CAG Lay Member
Mr David Evans	CAG Expert Member
Dr Tony Calland MBE	CAG Chair
Mr. Myer Glickman	CAG Expert Member
Ms Diana Robbins	CAG Lay Member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor

Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor
Prof. Matt Westmore	HRA Chief Executive

1. Introduction, apologies and declarations of interest

The Chair welcomed all Members to the meeting.

No apologies or declarations of interest were made.

2. Support decisions

Secretary of State for Health & Social Care Decisions

No non-research applications were reviewed at the **18 March 2021** meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **18 March 2021** meeting applications.

3. New applications – Research

a. 21/CAG/0056 – Population cancer screening clinical utility study (GRAIL)

Context

Purpose of application

This application from Grail Bio Inc and Kings College London (KCL) set out the purpose of a randomised controlled trial (RCT) that aims to understand whether the Galleri™ test (a Multi-cancer early detection (MCED) test) is a better way of detecting cancer early than the existing NHS pathway in people who do not have any symptoms of cancer.

The Galleri™ test is a new blood test that can detect signs of many different types of cancer in a single blood sample. If the Galleri™ test can find these signs earlier than other tests and before people have symptoms of cancer, it may mean cancer treatments that are less serious, less invasive and more successful can be utilised. NHS England has set an ambition to achieve a significant shift in the proportion of cancers diagnosed at an early stage by 2028. An intent of this study is to understand if the Galleri™ test can contribute to this aim. The RCT is consented and outside the scope for support.

Regulation 5 support is required solely for the activity of identifying potential patients by the processor(s) of this activity. This will be undertaken by NHS Digital (under the brand of NHS DigiTrials https://digital.nhs.uk/services/nhs-digitrials) and a sub-contracted third party mail-out company (APS) to send out invitation letters to seek consent. Potential participants will be identified via three methods, however Regulation 5 support has been requested for NHS Digital and APS, as a sub-processor, to undertake the invitation approach only.

Identification of the cohort will be undertaken by NHS Digital using the Personal Demographic Service (PDS) dataset to extract a cohort of eligible patients, and link to the National Cancer Registration and Analysis Service (NCRAS) to exclude certain cancer diagnoses. NHS Digital will apply the national data opt out, and PHE-specific opt out for the NCRAS data. Date of death will be checked in order to exclude any participants who have died. A pseudonymised invitation code for each individual is added to the dataset by the NHS Digital team.

NHS Digital will disclose name, full postal address, NHS Number, GP registration, and invitation code to APS in order to send the invitation letters to identified participants. Invitation letters will be sent out once only. Invitees will be invited to contact a study contact centre via a study website or phone if they are interested in participating, after which consent will be provided if participating. The central study team at KCL and Grail Bio Inc will only learn about the invitee when they contact the central study team to express interest in participating.

The recruitment process is expected to take 10-12 months after June 2021, but could take up to 18 months, and potential participants will be identified in monthly data extracts by NHS Digital. Identifying information is deleted by APS two weeks after each mailout.

A recommendation for class 3, 4 and 6 support was requested to cover access to the relevant unconsented activities by NHS Digital and APS 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	Approximately 1 Million people in the general population, not currently diagnosed with cancer (or within the last three years) aged 50-77 to be contacted by letter in order to obtain consent from 140,000 participants
Data sources	1. The Personal Demographic Service (PDS) dataset (held by NHS Digital) 2. The National Cancer Registration and Analysis Service (NCRAS). (PHE is the controller for NCRAS but data is held within NHS Digital currently for other COVID-19 purposes. PHE have provided permission for NHS Digital to use NCRAS data for this purpose if support is in place)
Identifiers required for identification and invitation purposes	Data items required for identification of cohort by NHS Digital: • Age • Sex • Postcode • Ethnicity • Date of death • History of invasive cancer diagnosis or treatment within the three years prior to the query • Current investigation for suspected cancer via the two-week wait pathway • Receiving hospice and end of life care through a Gold Standards Framework (GSF) Centre In order to send out patient letters the following identifiers are disclosed to APS: • Name • Address including full postcode

	• NHS number (as mentioned on letter) • GP registration (as mentioned on letter) • Invitation code (as mentioned on letter)
Additional information	NHS DigiTrials will extract lists of eligible participants approximately monthly for up to 18 months. However, if recruitment is slow or there are key groups under-represented then the number of extracts may be increased to weekly.
Areas out of scope	The applicant has stated that the following are outside the scope of this application and do not require support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002: 1. Identification of participants via query of GP practice records and invitation by GP. 2. Participant self-identification via an interested individual who presents after learning about the study from family member or friends, or from seeing the study recruiting in their area. 3. 'Phase 2' screening using the GP dataset held by NHS Digital is not yet ready to be supported and an amendment will be submitted in due course. 4. All flows of data after the time point participants consent to participate.

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.

The applicants attended the meeting and members thanked the applicants for their responses to CAG queries raised at that time.

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 were very strongly supportive of the concepts behind this application because it has a strong medical purpose and also a substantial public interest in supporting and encouraging appropriate participation in clinical trials.

However, as discussed at the meeting, the CAG expressed significant concerns that the application did not appear to fully address the principle of 'no surprises' as established by the National Data Guardian. Specific concerns are noted below but all members were clear that the concept of 'no surprises' must be respected to maintain the public interest, confidence and trust in line with this principle.

It was noted that this application may be followed by others of a similar design and it is also for this reason that it is important for this pilot application to embody principles that maintain and encourage a high degree of public trust. It is therefore essential that the principles of transparency and clarity are followed.

Scope of Support

It was stated in response to queries that NHS Digital will need to retain NHS Number and the date of mailing in order to prevent duplicate mailing, and that this would need to be retained for the duration of the recruitment period and 6 months after the recruitment period. Members were unclear on how the NHS number and the date of invitation is sent to NHS Digital, and whether support is required for a flow of NHS number and date of invitation letter from APS to NHS Digital. Clarity was requested on this aspect.

'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, should maintain public confidence 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.

An invitation letter from NHS DigiTrials was provided by the applicants, which refers to the Grail Bio Inc. website and will include the patient information leaflet which was also provided.

In response to queries regarding opportunities for opting out, the applicants stated communications will include a mechanism for individuals wishing to opt-out from being invited to take part. Text regarding this will be published on the NHS Digital website and this website will be made available approximately one month in advance of trial initiation. Members noted they had been provided with draft website text that was pending sign-off within NHS Digital.

The opt out option will remain on the website for the duration of the study. Social media communications starting approximately one month prior to trial invitation will include posts directing individuals where to opt out if they wish. This will also be done at monthly intervals for the duration of the study. The Grail trial website will also make available the same information directing individuals to the NHS Digital website to opt-out of the study.

The CAG had a number of concerns about patient notification, both in terms of prior to the breach of confidentiality occurring and at the point of invitation. To enable ease of advice provision the CAG comments are split below into four sections.

a. Notification - prior to the breach in confidentiality taking place

Members noted the trial protocol requires a disclosure before any members of the public can be involved to be asked for their consent. Therefore, members agreed it is imperative that considerable efforts are made to inform the general public about the trial before the breach has occurred, thereby reducing the risk of members of the public being surprised by the invitation to participate. Members commented that these communications are also important to avoid causing worry or confusion for the public, which might result in more general opt-outs and therefore undermine the purpose of the project and research as a whole.

Adequate and appropriate notification of the public is a typical element for all CAG applications given 'section 251 support'. The extent of the notification should be proportionate to the scale of disclosure, risk to public confidence and type of activity. For a project of this size, (at least one million invitations) the CAG considered that placing notices on websites and using social media alone would not suffice, also taking into account that the target age range may not be prolific users of social media when compared to other age ranges.

Members discussed previous precedents CAG had experienced regarding other applications aiming to contact large numbers of individuals, where the CAG had advised several different ways to ensure sufficient coverage to notify the target population. Among these were use of local radio and television, various social media outlets, local and national press with articles written by those supportive of the project. Other options include posters in bus shelters, or on the sides of buses, in gyms, council outlets, hospitals, GP practices and local clinics, and notices on websites of relevant charities, and health groups. This application is also targeting defined geographical areas which allows for considerable local penetration.

When questioned during the meeting regarding the detail of the proposed communication strategy, the applicant mentioned advertising in newspapers and on local radio, and additional means of communication, but there were no specific plans in place regarding this. As such, members requested a credible communications

strategy describing the proposals for the geographical areas concerned and a rough timetable to achieve the proposed plan. The timing should allow for the advertisement to be fresh in the minds of the public before the invitation letter are sent so as to respect the 'no' surprises' principle.

b. Website Text

The members commented on a number of issues regarding the website text, which are bullet pointed below for ease.

- The explanation of the function of CAG in the proposed website text is not accurate. It currently states: *'The Confidentiality Advisory Group, an independent body which provides expert advice on the use of confidential patient information in England has provided support*'. However, as the CAG is not a decision-making group and instead provides recommendations to the decision maker, the Health Research Authority in this case, this statement should be amended to include correct reference to the decision-making element. For example, *'The Health Research Authority, on advice from the Confidentiality Advisory Group, an advisory body which provides independent expert advice on the use of confidential patient information without consent in England and Wales, etc etc*

- The website text contains a statement that says *'details about potentially eligible participants to be provided to NHS Digital'.* The members commented that this does not appear accurate because details are not being provided to NHS Digital, rather NHS Digital are undertaking the identification of participants using databases they hold. This statement should be amended to accurately reflect what support is in place for.

- The members commented that the language used throughout the website text is not accessible to a lay person. For example:
    - *'How is personal data about potentially eligible patients processed?'* should be changed to something more simple such as "*how is information about me used?"*
    - 'Rights and complaints' could be changed to *'how do I opt out*?' as this is more accessible and likely to be read by viewers.

- A phone number, email address, and a postal address should be provided in order for people to opt out rather than only a weblink, noting CAG's previous point about utilising relevant communication channels typically used by the intended population.

- This website text should have an overall review by a patient and public involvement group, to ensure that the information is easy to understand.

c. Invitation Letter

The invitation letter will be the first point for many recipients where they become aware that their data has been used to invite them to the study. As such, it is imperative that the letter is clear about what has happened to date, to ensure clarity and maintain the public trust. The members commented on several issues regarding the invitation letter, which are bullet pointed below, for ease.

- The letter submitted does not have any logo on, however the applicants stated this would have an NHS logo. The CAG stated that this letter should be headed by the logos of NHS Digital, KCL and Grail. This provides clarity to recipients, as Grail is the company wanting to do the research, KCL is the joint controller (with Grail) and the data is held within and processed by NHS Digital. The CAG expressed this clarity and consistency to be the most appropriate route due to the specific nature and focus of the application, but Members noted that they would consider further justification for a different approach that maintains a similar level of clarity if thought necessary.

- The invitation letter is 'signed' by NHS England, however the connection between NHS England and the study is not clear in the letter. CAG understood that the aim of the clinical trial is to support better and earlier cancer diagnoses however, when considering the specifics of the application CAG advised further clarity on this necessity should be articulated.

- The CAG were unable to identify a strong rationale for inclusion of the NHS number on the invitation letter. In line with the requirements of Regulation 7 Health Service (Control of Patient Information) Regulations 2002 and UK data protection legislation, support is provided only to the use of identifiers that are justified as necessary to achieve the specified purpose. CAG were not persuaded by the justification that this is based around a potential participant possibly not knowing their NHS number. Members noted that if concerned a potential participant may not know their NHS number then other, less disclosive approaches should be considered. For example, patients can find out their NHS number using the following service, and details of the link can be included in the invitation letter or participant information sheet (https://www.nhs.uk/nhs-services/online-services/find-nhs-number/). It was stated in response to queries that NHS Digital will need to retain NHS Number and the date of mailing in order to prevent duplicate mailing, and that this would need to be retained for the duration of the recruitment period and 6 months after the recruitment period. Therefore it is unclear why NHS Digital cannot flag the 'code' against these stored NHS numbers and also retain GP details in order for the participant to link back to the details required after the participant has consented.

- Members agreed that insufficient justification had been provided for the inclusion of GP details on the invitation letter. This is due to the disclosive nature of these details, and the potential for confusion in giving the erroneous impression that the project had been approved by their GP, or that they are involved. Members ask the applicants to consider removing the GP details and instead consider using the code, which could be linked to their GP details by NHS Digital and provided to the applicant with the consent of the patient after they have enrolled into the study. If the applicants feel strongly that this is not possible, a stronger justification should be provided as to why an alternative to inclusion of GP details is not possible.

- Despite the applicants not justifying the use of the date of birth in the response to queries, and agreeing to delete this from the letter, the Committee felt that some households may have residents with the same name, but be of different ages, and therefore an additional way of distinguishing between people may be required. They suggested that month and year of birth or age in years may be a suitable alternative, which is less disclosive than date of birth. Consideration of this potential should be explored.

- Members commented that the letter does not detail to recipients how their data has been used, and by whom, in order to be invited, as well as the role of CAG. This should be included in the letter to provide clarity to recipients and be consistent across all communication channels. Members also noted that the letter should clearly explain that potential participant's clinical medical records have not been accessed, but their absence on the NCRAS database shows they have not had cancer.

- Members commented that the text of the letter needs to be clear that the person is being invited to take part in a research trial of a cancer test. It was commented on the reading of the invitation letter that invitees may mistakenly think they have been selected because they are suspected of having cancer. Members noted it was likely that the REC would also identify this point but thought it important enough to also flag.

- The '*what to do next'* section only covers what to do if the participant is interested in taking part. There is no comment about what to do if the participant does not want to take part. Clearly it is too late to opt out of any disclosure by the time the letter arrives, as the breach has already taken place, however the letter should clarify that their data will not be used in the trial or transferred to Grail Bio Inc or KCL if they choose not to participate, and that any identifying information held about them is deleted by the mailout company two weeks after the letter is sent.

- The invitation letter should be reviewed by a patient and public involvement group to ensure that it remains readily understandable to potential participants.

d. Participant Information Sheet

The Members commented on a number of issues regarding the participant information sheet, which are bullet pointed below, for ease.

- Noting that this element was likely to be considered by the REC as they have primary responsibility for participant information, the Members commented this initial participant information sheet seemed long, and may potentially overwhelm participants. The CAG asked that the applicant consider a layered approach of a shorter notification participant information sheet as part of the initial contact, leading on to the provision of a longer more detailed participant information sheet on request, perhaps including a link to the longer participant information sheet which could be on a website?

- The first line of the initial participant information sheet enclosed with the initial invitation states *'you are receiving this information sheet because you have contacted us about taking part'*. This is not correct as the participant will receive this as the first contact. It is important that this is changed and that clarity and consistency are maintained.

- On page 3, the purple box in the centre about the NHS says data is provided from National Disease Registration Service (NDRS). Members found this to be potentially confusing for patients, as it was their understanding that the data sources were the PDS service at NHS Digital and NCRAS data controlled by PHE. It is noted that although NCRAS makes up part of the NDRS, there should be full transparency about all the data sources, to avoid confusion.

- Noting that this activity relates to after participants have consented, the mention of pseudonymous data being sent to the US should be clear, with a lay definition of what pseudonymisation means in this case.

- Noting that this element was likely to be considered by the REC as they have primary responsibility for participant information, the Members commented that the term "blood draw" is not familiar to most UK residents. The CAG request that the wording of the participant information sheet is reviewed by a wider range of patient and public involvement participants to ensure plain language is being used where possible.

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 patient facing leaflets were stated to have been reviewed by six patient and public involvement representatives from a range of ethnicities and sociocultural backgrounds, in an event organised by KCL. It appeared to members that this review did not seem to specifically cover the use of confidential patient information without consent for this application. It appears some consultation was also undertaken by NHS Digital with 11 participants in relation to the 'NHS DigiTrials' broader infrastructure, rather than this specific 'pilot' activity. However, little detail has been provided about what the event was, what information the group was presented about the trial, any specific questions asked. Feedback showed the use of data without consent was generally considered acceptable, but no specific comments had been provided.

The CAG expect adequate patient and public involvement to be undertaken, and Members use the outcome of the patient and public involvement to provide assurance that patients feel the breach of confidence is justified by the public benefit of the project. Only then can the Committee make a judgement about the public interest in the work going forward.

Whilst the Committee does not expect very large groups of patients to be involved, there is an expectation for the patient and public involvement undertaken to be proportionate to the numbers of records where the breach of confidence will occur. For this application, this will be over one million individuals, with the possibility of this being higher, and becoming a significant proportion of the UK population. Members discussed this at the meeting with the applicants, who confirmed the information provided in the application. For this application the Members did not think that discussing the project with between 6 to 17 people was sufficient. As such, members agreed that further patient and public involvement work is to be undertaken with larger numbers of participants in order to discuss the acceptability of the proposed use of confidential patient information without consent, especially as the invitation letter will be a surprise to some members of the public despite the expected publicity.

The Members also commented that despite the target population where the breach is occurring being healthy volunteers, the disease area being studied in the trial is cancer. There are considerable patient and public involvement resources available through cancer charities, and the CAG suggested that this could also be a route to explore. The CAG also noted that if patient and public involvement is undertaken in the targeted geographical areas for the invitations that could also help in dissemination of the information about the project.

Role of NHS Digital (data processor vs data controller)

The issue of controllership was raised in the CAG meeting. Currently this application is under the joint controllership of GRAIL Bio inc and KCL with NHS Digital acting as a processor and APS as a sub-processor. However, members noted that when requesting copies of external communications, it appeared this development was being driven directly by NHS Digital, with sign-off appearing to take place only within NHS Digital. In reviewing the typical arrangements between controllers and processors, it did not appear that NHS Digital was operating as a traditional processor due to what appeared to be an enhanced role in determining the purpose and manner in which patient information would be processed. Members understood that NHS Digital is a custodian of national datasets and therefore has a separate controller role in that capacity that is completely separate to this application. However, this does not respond to the nuance regarding the apparent role of NHS Digital in determining the purpose and manner of processing of confidential patient information with regards to the invitation and other patient notification elements. The applicants are asked to provide further clarity on the role of NHS Digital as a data controller or processor and in particular, the role of Grail and KCL in authorising relevant communications being developed by NHS Digital.

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**

CAG had concerns about the need for including NHS number and GP details on the invitation letter. These concerns have been included in the invitation letter section to keep all queries related to the invitation letter together.

- **Feasibility of consent**

The application indicated that consent is not a practicable alternative due to the large numbers of potential participants. To reach the anticipated target will involve writing to one million individuals. The CAG recognised this justification of large numbers and agreed that consent would not be a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for identification of potential participants and in order to mail letters to invite participants to consent. It is not possible to undertake these tasks with anonymised or pseudonymised data. Comment on the extent of information to be included on communications is covered earlier.

Exit strategy

The expected exit strategy is consent. For participants who do not respond their information will be deleted by APS two weeks after the relevant mailout.

The expected enrolment period is 10-12 months from the anticipated start date of June 2021. The applicants have confirmed that support is requested throughout the invitation period in order to recruit the required 140,000 participants for the trial. Extracts of potential participants will be conducted for up to 18 months. As soon as recruitment targets are reached, NHS Digital will stop all extracts of eligible participants.

The CAG were content with this exit strategy, however the members would like further confirmation that APS would delete all identifying information including NHS number and GP details within two weeks of sending the invitation letters.

Size of cohort

The applicants are basing this application on one million letters to be sent in order to achieve a participation rate of 140,000 consented patients. The Committee queried whether the expectation of a 14% return is realistic and requested that the applicants consider whether they may require support for access to a larger cohort in order to achieve the predicted recruitment rate Noting the applicants were intending to also combine this specific application approach with other approaches, members noted that a similar activity had had to return to CAG for the reason of poor uptake. This is in order to avoid an urgent amendment later.

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 explain why NHS Digital is considered a processor for this application in the context of the points raised in the letter. This should also include clarity on the decision-making and sign-off for relevant activities by KCL and GRAIL in their capacity of joint controllers, and how NHS Digital decision-making process fits in with its processor role.

2. Please confirm if support is required for the flow of NHS number and date of invitation letter sent from APS to NHS Digital.

3. Please provide a credible and appropriately detailed plan for a communications strategy prior to the breach in confidentiality occurring, describing the specific proposals for the geographical areas concerned and a rough timetable to achieve the proposed plan.

4. Please provide an updated version of the website text to the CAG. Improvements made should be based on the suggestions below:

    a) The explanation of the function of CAG should be corrected.
    b) Incorrect statements regarding data flow should be corrected.
    c) Language should be amended to be more accessible and headers should be entitled more clearly.
    d) Opt out contact details should be provided.

5. Please provide an updated version of the invitation letter to the CAG. Improvements made should be based on the suggestions below:

    a) Consider an NHS logo, KCL logo and Grail logo on the letter, or provide stronger justification if this approach is not considered appropriate.
    b) Ensure the connection between NHS England and the study is clear, or consider an alternate signatory.
    c) Remove NHS number from the letter.
    d) Remove GP details from the invitation letter, or provide a stronger justification as to why an alternative is not possible.
    e) Consider if month and year of birth or age in years should be used on the invitation letter.
    f) Ensure the text is clear regarding that person being invited to take part in a research trial of a cancer test.
    g) Ensure the text is clear regarding how the participant has been contacted to avoid any mistaken perceptions.
    h) The role of CAG and the legal basis of the participant identification and invitation process should be clearly explained.
    i) The letter should explain what happens if the participant does not take part.

6. Please provide an updated version of the participant information sheet to the CAG. Improvements made should be based on the suggestions below:

    a) Consider a layered approach.

b) Remove the statement *'you are receiving this information sheet because you have contacted us about taking part'*, and ensure clarity and consistency throughout.
c) Ensure the data sources are clearly explained.
d) Ensure the pseudonymous data flow to the USA is clearly explained.

7. Please undertake further patient and public involvement with a larger group of people.
   a) This should specifically discuss this use of confidential patient information without consent, and detailed feedback of the events should be provided to the CAG.
   b) A patient and public involvement group should review the entire suite of intended communications.
   c) Please consider undertaking patient and public involvement with cancer charities, and in the geographical areas where the invitation letters will be targeted.

8. Please confirm that APS will delete all identifying information including NHS number and GP details within two weeks of sending the invitation letters.

9. Please consider whether support may be required for a larger cohort of individuals to be screened and posted an invitation letter.

10. Please provide the Favourable Opinion from the REC when this becomes available

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **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.

   Confirmed:
   - The NHS Digital **19/20** DSPT review for **APS (Allied Publicity Services (Manchester) Limited** and the **19/20** DSPT equivalent for **NHS Digital** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 20 April 2021).

- NCRAS data is controlled by PHE, however NHS Digital currently hold this and therefore this data is subject to NHS Digital's governance.

4. New applications– Non-Research

a. 21/CAG/0047 – Neonatal Intensive Care Data to be provided to the National Pregnancy in Diabetes Audit (part of the National Diabetes Audit)

Context

Purpose of application

This application from NHS Digital set out the purpose of a non-research application seeking to link the National Pregnancy in Diabetes (NPID) audit dataset to the National Neonatal Research (NNRD) database in order to improve data collection and to better look at outcomes for babies who are born to a diabetic mother.

The applicants are seeking support to link the NPID dataset to neonatal data in order to improve the collection and to better look at outcomes for babies who are born to a diabetic mother. The applicants will investigate whether the outcomes of women with pre-existing diabetes and their babies are different to the general population and will also examine if there is a higher instance of admissions to neonatal intensive care and if these admissions are for longer periods. The findings can then be used to inform changes to the diabetes service for women of childbearing age. Under the work package deliverables set by NHS England and after discussion with the NPID specialist advisory group, it was decided that information on neonatal length of stay and outcomes is required in order to see the full patient journey. The applicants opted to link to the NNRD as the required information is already collected for this database and, by using this existing information, the burden on NPID participants will be eased as will not need to enter any further data. The NNRD has existing support under CAG reference ECC 8-05(f)2010 to enable routinely collected patient identifiable data to be populated on this research database and for onward disclosure of confidential patient information to researchers. Researchers applying to access data from the NNRD must apply via the Neonatal Data Analysis Unit Data Steering Board.

The NPID audit is part of the National Diabetes audit undertaken by NHS Digital and is directed under s254 of the Health and Social Care Act by NHS England. The applicants will disclose a list of NHS numbers and patient dates of birth from the NPID at NHS Digital to Imperial College London for linkage to NNRD. Imperial College London will match the patients to their records and return a linked dataset, containing patient

outcomes, to NHS Digital. All patients in Wales are recruited on a consented basis. Until 31 December 2017, when NHS England directed NHS Digital to undertake the audit under s254, patients in England were recruited on a consented basis. Support is therefore only sought for the processing of confidential patient information for patients in England included in the NPID from 01 January 2018 onwards.

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

Cohort	All pregnant women in England with pre-existing diabetes that have been entered into the NPID audit since 01 January 2018. The babies of women in the cohort who were admitted to neonatal care after birth.
Data sources	1. The National Pregnancy in Diabetes dataset at NHS Digital 2. The Nation Neonatal Research Database at Imperial College London
Identifiers required for linkage purposes	1. Mother's NHS Number 2. Mother's Date of birth 3. Mother's Postcode – unit level
Identifiers required for analysis purposes	1. Mother's NHS number 2. Mother's DOB 3. Baby's NHS number 4. Baby's DOB

Additional information	Patients in Wales and the Isle of Man, as well as English patients recruited prior to 31 December 2017, are outside the scope of the Regulation 5 support sought.

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 CAG agreed that the application was in the public interest and had a medical purpose.

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 justification given in the application is that patients consent to inclusion in the NPID. This isn't relevant to the cohort that is the subject of this application, as they have not previously been approached for consent. The CAG agreed that the argument for not seeking consent had not been well made, but that consent was not practicable due to the potential size of the cohort and that contacting the parents of children who required neonatal case may be distressing for the parents.

- Use of anonymised/pseudonymised data

Confidential patient information is needed to link the NNRD to the NPID. The CAG agreed that this cannot be done in any other way.

'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 NPID information leaflet for English patients was provided. This referred to the change in legal basis since 2018, so that consent no longer needs to be sought for patients in England. Email, telephone and postal contacts were given for NHS Digital for patients to ask queries. Patients were also asked to use these contact details if they had consented during a previous pregnancy and now wished to withdraw consent. Patients were advised to speak to their clinician if they wanted to opt-out of data collection for their current pregnancy.

A poster for NPID was also provided. The poster advised that patients could contact NHS Digital by telephone or email to register dissent, and included telephone and email contact details.

The linkage to NNRD was not referred to in the leaflet or poster. In their responses to queries raised by the Confidentiality Advice Team, the applicant provided the text that will be used on the NHS Digital NPID webpage. This referenced the linkage to the NNRD and included an email address to register dissent.

The applicant explained that the National Data Opt-Out did not apply to the NPID as it is collected under s254 directions. Patients were still able to contact NHS Digital and request the removal of their data, and the applicants would ensure that the website and patient communications explain that patients can opt out of this element of the collection. If an individual request to be removed from this linkage is received, then the applicants will delete all data pertaining to that person, including the outcomes received from the Imperial College.

The applicants have not specified whether the National Data Opt-Out will be applied to the processing of confidential patient information under s251.

The CAG asked that improvements were made to the patient notification materials and website information. The updated website information was to be provided to the CAG within 6 months of the issuing of the CAG outcome letter and the updated notification materials at the first annual review. Members recommended that the further patient and public involvement requested below also included review of the notification materials. The CAG also agreed that telephone, email and postal contacts needed to be provided on all notification materials, including the website information.

The Decision Maker for the Secretary of State for Health and Social care requested that this application was included on the Imperial College London website, in the area where current projects using the NNRD as listed.

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 explained that they worked closely with Diabetes UK for all aspects of the NPID. They had consulted the NPID Advisory Group, which includes 3 patient representatives. The representatives agreed that the data linkage would be potentially beneficial and were supportive of changes that will improve the outcomes for diabetic women.

The applicants did not feel that a wider patient group needed to be consulted and no further patient and public involvement was planned. The applicants did state that, if the linkages proposed in this application were approved, then a bulletin would be sent out to all audit participants and the website would be updated to inform participants of these linkages.

The CAG agreed that further patient and public involvement would need to be undertaken with a larger group. The processing of confidential patient information without consent as proposed in this application needs to be discussed. A report will need to be given to the CAG during the first annual review.

Exit strategy

Once the linkage has been carried out and the linked dataset returned to NHS Digital, the NNRD will remove the identifiable data provided by NHS Digital from their system. NHS Digital will hold the linked dataset for two years.

The applicants explained that the data linkage will be a one-off request at this point, however the linkage may be repeated in 2023. The applicant noted that NHS Digital plan to move the NNRD from Imperial College London to NHS Digital, so that it will be an information/data standard held by NHS Digital. If this move takes place before the linkage is repeated, then support under s251 will not be needed for the repeat linkage.

The CAG noted a lack of clarity over how long the confidential patient information would be retained, as both 2 and 5 year periods were referred to. Members noted that the lack of certainty over how long the confidential patient information will be retained may be due to the planned move of the NNRD to NHS Digital. The CAG asked that the applicants provide an update on the move of the NNRD to NHS Digital in the annual reviews and confirm within 4 years of the issuing of the supported outcome whether the move will take place.

Cohort size

The CAG noted that the number of patients included in the scope of Regulation 5 support is not clear. The applicants were to provide at the first annual review the

approximate number of patients who would come under the scope of the Regulation 5 support, e.g. those included on the NPID since 01 January 2018.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Within 6 months of the issuing of the supported outcome the applicants are to provide revised website information.

2. In the first annual review the applicants are to provide the following:

    a. Further patient and public involvement is to be carried out, with a larger group of patient representatives, and feedback provided to the CAG.

    b. Revised patient notification materials are to be provided. Telephone, email and postal contacts need to be provided on all notification materials, including the website information.

    c. Confirm the approximate number of patients who would come under the scope of the Regulation 5 support, e.g. those included on the NPID since 01 January 2018.

3. Within 4 years of the issuing of the supported outcome, provide an update on the move of the NNRD to NHS Digital and confirm when this will take place.

4. This project is to be included on the Imperial College London website, in the area where current projects using the NNRD as listed.

5. 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 **2019/20** DSPT reviews for **NHS Digital** and **Imperial College London – Faculty of Medicine – Neonatal Data Analysis Unit** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 16 April 2021).

5. New applications – Research

a. 21/CAG/0050 – Suicide in former service personnel of the UK Armed Forces

Context

Purpose of application

This application from the University of Manchester set out the purpose of medical research that seeks to investigate suicide risk amongst those who have left the UK Armed Forces, and to make comparisons with serving personnel and the general population.

Suicide accounts for almost 6,000 deaths per year in the UK and prevention is a health priority. Previous international studies have examined the incidence of suicide in former military service personnel, as well as risk factors associated with suicide. Studies in the United States have shown veterans to have a higher rate of suicide compared to the US general population. Increased risks have been found in men, those with depression or alcohol-related problems, as well as those subject to early discharge. A previous study conducted by the applicants had found that 224 veterans died by suicide within a cohort of 233,803 individuals who had left the UK Armed Forces between 1996 and 2005. Although the overall rate of suicide was not greater than that in the general population, the risk of suicide in men aged 24 years and younger who had left the Armed Forces was approximately 2 to 3 times higher than the risk for the same age groups in the general and serving populations. The risk of suicide for men aged 30-49 was lower than that in the general population.

Since this study was carried out, there has been no systematic investigation of suicide in UK veterans. It has been suggested that these individuals may be a potentially vulnerable group because of prior adverse life events, the difficulties associated with the transition to civilian life and high rates of homelessness and alcohol and substance misuse. The UK Armed Forces is just ending a period of very intensive operations. A range of new services for veterans may have improved access to mental health care. There is potentially greater public awareness and reduced stigma associated with mental health problems. In the general population, men in mid-life are now the group at

highest risk of suicide. The applicants seek to undertake a new study to examine suicide in those who have left the UK Armed Forces to provide information to be used to inform preventive efforts.

The study will consist of two phases;

Phase 1 - the applicants will conduct a retrospective UK-wide cohort study. The data flow is:

- The Ministry of Defence will transfer data from the Service Leaver's Database (SLD), which does not contain patient information, to the NCISH research team.
- The applicants will link the SLD data to the NCISH general population suicide database, in order to identify patients who died by suicide/undetermined death.
- The data for those who could not be linked to the NCISH general population dataset, i.e. those who are still alive or who died by means other than suicide, will be deleted.
- The linked dataset will be pseudonymised at this point and a unique identifier applied.
- The unique MoD number and unique NCISH identifier will be transferred to the MoD so that the MoD can include additional data fields relating to demographics and military service from MoD SLD and healthcare from MoD data on this "suicide cohort". The dataset will then be pseudonymised.
- The MoD will also create a new dataset, using the SLD, where they will remove the "suicide cohort" from the SLD. This new, anonymised dataset will contain data on demographics, military service and healthcare from MoD data for living discharged personnel and discharged personnel who died by other causes. No identifiers will be included in this dataset. The MoD will also provide the NCISH with an extract from the MoD Deaths database for all in-service deaths from suicide or probable suicide in service personnel between 1998 and 2018.
- The NCISH research team, using a mixture of identifiers, will link this data to NCISH's general population suicide database. The general population suicide database includes a unique identifier that links NCISH general population suicide data to NCISH data on patient suicide deaths.
- Once linkage is complete all identifiers will be removed from the linked data, and unlinked data will be deleted.
- The pseudonymised dataset will be linked to NCISH's database of suicide deaths in people in recent contact with mental health services (patient suicides) using an existing unique NCISH identifier.

Phase 2 – the applicants will collect data on the factors related to suicide from other official source, such as coroner's records, for veterans who died by suicide. The applicants will apply random sampling to identify 200 patients from the dataset of veterans who died by suicide between 2007 and 2018. The applicants will then contact the relevant coroner by letter, which will include the patients name, date of birth and

date of death, to request any information they have on that individual. This request will include audio copies of the inquest recordings, which are usually on CD but other formats will be requested if possible, from the Senior Coroner of the jurisdiction where the death occurred. If audio recordings are not available, the applicants will request copy statements or depositions and other relevant reports, such as post-mortem and toxicology reports, submitted as evidence during the inquest.

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	Phase 1: 415,000 patients aged 16 years and over who are former service personnel of the UK Armed Forces, who died by suicide or probable suicide between 01 January 1996 and 31 December 2018. Phase 2: 200 patients aged 16 years and over who are former service personnel of the UK Armed Forces, who died by suicide or probably suicide between 01 January 2007 and 31 December 2018.
Data sources	Phase One 1. From the Ministry of Defence: a. The Service Leaver's Database, b. Deaths Database, c. Additional MoD data on education status, medical deployability status at exit, history of unlawful activity, disciplinary actions including military prison, whether failed a compulsory drug test, tariff descriptor for AFCS claims, marker for whether treated in Department Community Mental Health (DCMH), and mental health diagnosis if treated in DCMH. 2. From the National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH), held by the University of Manchester: a. General population suicide database, b. Patient suicide database

	Phase Two 1. Coroner inquest records, obtained from the Senior Coroner of the jurisdiction where the death occurred
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Date of death 4. Postcode – unit level 5. Place of death 6. Gender
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – district level 4. Gender 5. Ethnicity
Additional information	The Department Community Mental Health (DCMH) service are an outpatient mental health service for serving personnel of the Armed Forces. They are commissioned by the MoD and run by the NHS.

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 was in the public interest and had a medical purpose.

Scope

The CAG noted that support under Regulation 5 was needed for the transfer of confidential patient information from NCISH to the coroners, but queried whether support was required for the transfer of confidential patient information from the coroner to NCISH. Under section 27(2) of the Coroners (Investigations) Regulations 2013, the coroner may provide any document or copy of any document to any person who in the opinion of the coroner is a proper person to have possession of it. Therefore, this

disclosure may be outside the scope of the Regulation 5 support sought. Members asked that the applicants clarify whether support is required for this disclosure.

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 applicants explained that consent could not be sought from those who had died by suicide or by other means. The CAG agreed that a stronger justification needs to be provided on why consent cannot be sought from the living veterans whose information will be processed.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link patients in the MOD held databases to the NCISH database, and to contact the coroners.

Data for a number of veterans who may be alive will also be processed. Following queries by the CAT, the applicant has revised the data flow to minimise the use of identifiers from living veterans.

The CAG asked if full dates of birth and death needed to be retained, or whether these could be revised, e.g. year of birth only and age at death.

'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 advised that notification cannot be conducted for the deceased members of the cohort. The applicants advised that the MoD Privacy Notice included information on the use of data and how service personnel can request the erasure of their personal information and how to withdraw consent for specific processing. Information will also be made available on the NCISH website.

If a patient has opted out of their health data being used for anything other than care and treatment, then their opt-out will be applied by the relevant health organisation, and their health data will not be shared with NCISH.

For the MoD records, if there is a marker on the military medical record indicating whether a service person has opted out of the sharing of their medical data with a third party, then their records will not be shared.

If a coroner informs the applicant that they do not want to participate in the study, or the coroner is aware that the deceased persons' family/next of kin has objected to sharing of the records, then this will be respected.

The CAG agreed that the notification materials need to be improved. The focus of the research was those who had died by suicide, however a lot of information would be processed for those who died by other causes or who were still alive. The information processed was also potentially very sensitive. Members agreed that further efforts needed to be made to inform patients and their relatives that this research was taking place. The further patient and public involvement requested below should include how the materials can be improved.

The applicants had noted that the National Data Opt-Out would be applied, but it was unclear how this would be done. The CAG asked that an explanation on how the Opt-Out would be applied was provided.

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 explained that they planned to hold regular progress meetings with a study-specific project board, which will include representatives from the MOD, NHS England and the University of Manchester. The MOD will also set up an oversight board, who will help with disseminating the study findings.

The applicants had also engaged with people with lived experience of suicidal behaviour from the Centre for Mental Health's Lived Experience panel. They also engaged with veterans and people bereaved by suicide from NHS England's Patient and Public Voice Group, who provided feedback on the study documentation. The Lived Experience panel will also comment on draft reports and associated infographics, to ensure that they are presented in a format suitable for different audiences.

The applicants provided further details on the patient and public involvement carried out. The applicants engaged with two patient and public involvement groups, Mutual Support for Mental Health (MS4MH) of the Centre for Mental Health and Safety and Patient and Public Voice Group of NHS England. It isn't clear from this document whether views were sought specifically about the use of confidential patient information. The applicants advised that further patient and public involvement is planned as the study continues.

The CAG agreed that further patient and public involvement was needed to provide evidence of patient and public support for the processing of confidential patient information without consent as proposed in the application. Members suggested that the applicants collaborate with organisations such as those that provide support to veterans and those that support the families of those who committed suicide.

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. Clarify whether support is needed for the disclosure of patient information from the coroners to the University of Manchester.

2. Provide a stronger justification on why consent cannot be sought from the living veterans whose information will be processed.

3. Advise whether full dates of birth and death need to be retained, or whether these can be rendered less identifiable.

4. The patient notification materials need to be improved.

5. Further efforts need to be made to inform veterans and their relatives that the research is taking place.

6. Further patient and public involvement needs to be carried out, particularly around the processing of confidential patient information without consent as proposed in the application and around improvements to the patient notification materials.

7. An explanation on how the National Data Opt-Out would be applied is required.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 16 December 2020.**

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 **2019/20** DSPT review for The National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (16 April 2021).

   Pending: The DSPT for the Ministry of Defence is pending.

b. 21/CAG/0042 – The Wynn Database – Metabolic Risk Factors and Mortality v1.0

Context

Purpose of application

This application from Imperial College London (ICL) set out the purpose of medical research of creating 'the Wynn Database', which will hold metabolic data concerning cholesterol and glucose levels. This information has already been collected between 1965 and 2000 by Professor Victor Wynn's group, for clinical and research purposes, from 14,615 individuals who attended various clinics run by Professor Victor Wynn. The database has been retained in the public interest up until this point, as the database is a valuable research resource. As part of this application the applicant is requesting support under Regulation 5 for the ongoing retention of the Wynn Database until the point it is pseudonymised, to ensure a legal basis under common law. The applicants plan to link the database to age at death and cause of death, as this will enable extensive retrospective and prospective analyses of relationships between metabolic risk factors, mortality and cause of death. The applicants will then delete all identifiable information from their database, however support is still required for NHS Digital to undertake annual linkages with mortality data which will then be provided to the applicant in pseudonymised format.

The applicants propose to use this resource as a research database to enable future research to be undertaken using pseudonymised data, as the Wynn Database will provide a more comprehensive understanding of metabolic risk factors, their inter-relationships and how those inter-relationships might contribute to cardiovascular disease, diabetes and cancer. Establishing a long-term future for the Wynn Database will enable a range of further investigations relating to risk factor inter-relationships and the relationships of risk factors to cause of death.

Currently, the Wynn Database is contained in two electronic files at ICL:

- One containing non-identifiable clinical information, alongside a unique database number, including age, year of birth, gender and ethnicity.
- The second contains identifiable information and is securely stored separately from the clinical dataset, alongside the unique database number.

The identifiers held are forename, surname, initial, date of birth and gender and last known postcode. ICL will add an additional unique ID - member number to each individual. ICL will then disclose the file containing identifiable information to NHS Digital. NHS Digital link the Wynn database identifiers with the Personal Demographics Service (PDS) In order to find the NHS number, and then link with ONS mortality data. Age of death, cause of death, and member number will be returned to the applicants, who will then link the mortality data to the clinical dataset using the member number. Once linkage has been undertaken, applicants will delete all identifiable information, including their copy of the Wynn Database identifiable information file and any paper records. The database will be retained in pseudonymised format. The original Wynn Database record database number will be replaced by the member number, and the original database number will be eliminated from the Database, however a key that links member number to original database number will be retained by the applicants, separated from the other information, should the need arise to cross-reference future Wynn Database analyses with previous analyses of data included in the Wynn Database, for the duration of the database being in existence. NHS Digital will retain a key linking member number to identifying information, in order to provide the applicant annual mortality updates, in principle until all participants have died.

As the database will be pseudonymised it will not be possible for any investigators, including the applicants, to link either member number or database number to personal identifiers. Access to the database will be via research proposals and protocols developed by or in consultation with the Head of the Section of Metabolic Medicine, with review by and discussion with other members of the Management Group. As the database is relevant to the research specialities of the Section of Metabolic Medicine, it is expected that the great majority of proposals will be generated within the Section of Metabolic Medicine at Imperial College London.

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

Confidential patient information requested

Cohort	14,615 individuals; This encompasses everybody who attended the Department of Metabolic Medicine and the Wynn Institute to provide a blood sample, with data collected between 1965 and 2000.
Data sources	1. The Wynn database (Held by Imperial College London) 2. NHS Digital; • Office for National Statistics (ONS) Mortality dataset • Personal Demographics Service (PDS)
Identifiers required for linkage purposes	In order to facilitate first linkage with PDS: 1. Unique ID - member number, 2. Name, 3. Date of birth, 4. Gender, 5. Postcode In order to facilitate linkage with ONS mortality outcomes: 1. NHS number derived by NHS Digital from PDS, also used to link to mortality data by NHS Digital, but will not be accessible to the applicants 2. Unique ID - member number
Identifiers required for analysis purposes	1. Age 2. Year of birth 3. Gender 4. Ethnicity 5. Unique ID - member number

	Unique ID – original database number retained separately from the database. This can be considered pseudonymous.
Additional information	NHS Digital will hold the key linking member number to personal identity in order to provide annual mortality updates to the applicant, in principle until all participants have died. ICL hold a key for member number to database number for the duration of the existence of the database.

Confidentiality Advisory Group advice

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 understood the historical value of this dataset, understood the rationale behind the application, and were assured that this application 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.

- **Feasibility of consent**

The applicants reason that consent is not practicable, as the Wynn Database contains information collected between 1965 and 2000, and contact details no longer exists for most individuals. For those with contact information still recorded, it is over 20 years old and is likely to be unreliable. Therefore, to find out up to date contact details would involve further disclosures of identifiable information.

The CAG accepted this justification.

- **Use of anonymised/pseudonymised data**

Identifiable data is required for annual linkage of identifiers of all people in the Wynn database to age at death and cause of death by NHS Digital. This cannot be done without the use of identifying information. The file containing identifiers will be held by the applicants only for as long as it takes NHS Digital to complete linkage of Wynn Database member numbers to NHS number, prior to provision of age at death and causes of death by NHS Digital. After that, full pseudonymised working will be established. Rather than date of birth, participant age will be held in the Wynn Database.

The Members accepted that the applicants require identifying information in order to undertake linkage only, and that the database would be managed in a pseudonymised manner that could not be minimised further.

'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 Wynn Database is described on the website for the Imperial College Section of Metabolic Medicine which has a link to a privacy notice. The applicant has provided an updated privacy notice in response to queries, which contains an opt out option and has been reviewed by two lay individuals. It is long and detailed, however the content seems well explained.

The applicant has developed a Wynn database opt out option for this application via NHS Digital. NHS Digital will provide the Database management team with the relevant member number and that participant's data will be removed. NHS Digital will also apply the national data opt out.

The CAG felt that the privacy notice was too long, and suggested a layered approach of a shorter patient notification which then links on to a longer more detailed privacy notice. They also felt it could be a bit clearer, with more specific information regarding the use of the Wynn database instead of more general information which seems not relevant to this application. For example the Committee noted the section on the potential for international transfer of data seems not necessarily relevant to the Wynn database, and may have come from a more general Imperial College template.

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 applicant has circulated the updated privacy notice to 20 members of the Metabolic Medicine and Diabetes Clinical Research Patient and Public Involvement Group, which does make it clear that the processing is being undertaken without consent, however the two responses received only provided feedback on the privacy notice rather than providing explicit support for this processing of confidential patient information without consent.

The Committee considered that the patient and public involvement undertaken was limited, and the applicant should undertake more. The acceptability of the proposed use of confidential patient information without consent is required to be specifically addressed.

Exit strategy

It is estimated that the identifiers will be deleted from the Wynn database within a period of 2 years, to allow for linkages to be undertaken. Once pseudonymised, non-identifiable data will be kept indefinitely by Imperial College London. However, support is required until the annual linkages with mortality data end – which is requested indefinitely, as this will be required until the last participant dies, and it is not possible to predict with accuracy when this will be.

The CAG members understood the rationale for requesting mortality updates until the last participant dies, however support is provided for five years in the first instance, due to the changing information governance landscape. An Amendment will be required in five years time, to extend support.

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

The following sets out the specific conditions of support.

1. Support is provided for five years in the first instance, and at this point an amendment should be submitted to extend the duration of support.

2. Please provide updated patient notification within **three months** from the date of this letter, which is;
   - layered into a shorter notification, and then a longer privacy notice,
   - clearer with more specific content regarding the Wynn database, and with any irrelevant sections removed.
3. Please undertake further patient and public involvement, specifically discussing the acceptability of the proposed use of confidential patient information without consent, within **three months** from the date of this letter.

4. Favourable opinion from a Research Ethics Committee. **Confirmed 12 April 2021**

5. 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 **19/20** DSPT review for **Imperial College London - School of Public Health Medical Trials and Research (EE133887-SPHTR)** and the DSPT equivalent for **NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 19 April 2021).

6. Any other business

No other business was raised.

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

Signed – Chair	Date
Minutes signed off via correspondence by Dr Tony Calland, MBE, CAG Chair, and Dr Will Bernal, CAG Alternate Vice Chair	21/10/2021

Signed – Confidentiality Advice Team	Date
Katy Cassidy	21/10/2021