Minutes of the meeting of the Confidentiality Advisory Group

22 September 2022 via Zoom

Present:

Name	Role
Dr Tony Calland, MBE	CAG Chair
Ms. Clare Sanderson	CAG Alternate Vice Chair
Dr Martin Andrew	CAG Member
Professor Lorna Fraser	CAG Member
Dr Rachel Knowles	CAG Member
Dr Harvey Marcovitch	CAG Member
Mr Andrew Melville	CAG Member
Ms Rose Payne	CAG Member (Left after 4a)
Ms Diana Robbins	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Mr Will Lyse	HRA Approvals Administrator

Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Rob French	Observer (Senior Research Fellow from Cardiff University)
Sarah Graves	Observer (HRA Approvals Officer)

1. Introduction, apologies, and declarations of interest

CAG member Dr Katie Harron gave apologies.

There were no conflicts of interest declared.

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 **25 August 2022** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **25 August 2022** meeting applications.

Minutes:

The minutes of the following meetings have been ratified and published on the website: **25/08/2022**

3. Consideration Items - Annual Review

a. ECC 1-05 (b) 2012 - ALSPAC Study Young Adults: Enrolment and Consent for record linkage

Health Research Authority decision

1. The Health Research Authority confirms the annual review is satisfactory.

2. All pre-existing specific and standard conditions remain applicable.

3. This letter has been issued as updated conditions of support have been applied. See 'specific conditions of support (updated)' section.

Annual review outcome

As a whole, it was noted that the activity was proceeding as planned and the justification for continuing support had been satisfactorily made. The CAG would like to state that they understand the importance of this long-term study and are very supportive of ALSPAC. The Members spent a considerable time reviewing the details provided, and because of the huge breadth of ALSPAC in its entirety and the age of some of the applications there are a considerable number of queries which the CAG feel are important to help ensure that the regulatory support is brought up to date and in line with current practice.

However, as the annual review indicated that conditions of support were pending, consideration of the annual review was carried out by the full CAG at the 22 September meeting.

This letter should be read in conjunction with the conditions of support change letter issued on 29 March 2022.

Additional Conditions of support (29 March 2022)

The ALSPAC application has been supported since 2013 as a research database (ECC 1-05 b 2012). The ALSPAC cohort originated as a consented study, and 's251' support was requested for linkages to various datasets.

However, as this was submitted to the ECC 10 years ago, and as a result of recently reviewing one of the ALSPAC sub-studies, the 2022 annual review has been submitted for full CAG review in order to clarify some additional conditions that were assigned;

1. Each annual review for ECC 1-05(b)/2012 will be reviewed at a full CAG meeting.

This condition is met for the conditions of support change letter, and remains for the lifespan of the application.

2. An updated diagram should be provided at the next annual review, clearly showing the organisations involved, the specific datasets linked, and which flows require 's251' support, as per advice in this letter.

The applicant provided an updated data flow diagram, which the Members were content to accept for the purposes of meeting this condition.

3. This diagram should clearly show what data is already retained in SAIL, providing clarity on criminal record data, education data and free text, as per advice in this letter.

The CAG were content to accept this description, noting that criminal record data, education data, and any other non-health data was not in scope for 's251' support, and that no free text data is retained.

4. Please specify how often additional follow-up linkages are requested, as per advice in this letter.

The applicant has supplied information on how often linkages are undertaken within the annual review, and this is different for each dataset. The CAG were content that the applicant had met the condition of support.

5. This diagram should also show for each data flow, what proportion requires 's251' support, and what proportion is processed with consent as the legal basis under common law, and updates should be provided annually regarding the number of individuals who either consent or decline to the linkage element of ALSPAC.

The data provided answers this for most of the data sources, however the answer for AvonCAP was listed as 172 participants (xx consented, xxx under s251). Please can this be clarified? This is added as a new condition, and so the current condition can be considered met.

Updates should be provided annually regarding the number of individuals who either consent or decline to the linkage element of ALSPAC, and this condition has therefore been included again for the next annual review. This aligns with original condition 6c) 'Confirmation of further efforts made to inform the cohort of the data linkage activity and details of how many indications of dissent have been expressed following this.'

As part of the annual review provided, the applicant has informed CAG that the consent campaign has now gained responses from 5,758 participants (43% of the 13,238 contacted). However, this has remained static since 2018, due to a hiatus in the young persons clinic. It appears the proportion of individuals consented is 44% in 2022. The CAG would like to be clear that they do expect continuing efforts to seek consent. This is expanded upon in a further section below.

6. Please describe the process to add a sub-study to the ALSPAC protocol, particularly those that require additional 's251' applications. If participants are consented for a sub-study, are they also approached about consenting to linkages for main ALPSAC?

The applicant has described the current system for adding a new sub-study to the ALSPAC protocol, which has clearly been well developed over a long time. There appears to be no specific data access committee, although this role appears to be fulfilled by the ALSPAC executive team, who review every project submission. The executive team refer to the Scientific Director (SD) for issues regarding scientific direction, the Board for unresolved issues/problems and to the Independent Scientific Advisory Board (ISAB) for data and sample access requests that it has been unable to adjudicate on. For access to data to be granted, the researchers need to demonstrate that their proposal is an appropriate and ethical use of the data, that it will deliver clear public benefits and that they will publish their results. research using linked health records is subject to a Data Protection Impact Assessment (DPIA) before commencing.

The applicant confirmed in the annual review that collecting consent is built into protocols when participants attend any clinical assessment visits, sub-study investigations or join the CoCo90s (Children of the Children of the 90s) project enrolling the third generation of study participants. The CAG would like to remind the applicant that these conditions were brought on after the review of a sub-study, where it was not clear that consent for ALSPAC linkages was being sought, hence the query, and so this should be made clear to any researchers who have contact with ALSPAC participants, as this is a good opportunity to seek consent, and exit 's251' support for those patients.

The CAG agreed this condition is met.

7. Please describe the process undertaken for the addition of each new sub-study with regards to the original cohort advisory panel (OCAP) and the ALSPAC ethics and law committee (ALEC) procedures.

The applicant provided a description of ALEC and OCAP, and therefore the condition is met, however a further condition has been added, as It is still unclear whether all applications go through a process that involve OCAP and ALEC.

Regarding OCAP, it is clear to CAG that this is a lay advisory panel made up of 30+ study participants. However it is not clear what proportion of the ALSPAC sub-studies/requests for data are reviewed by OCAP, especially those requiring ‘s251’, as the applicant response merely lists it as a potential, and states that researchers may be invited to submit their project documentation, or to attend OCAP to discuss their proposal.

Regarding ALEC, which is ALSPACs own independent ethics committee, it is not clear when ALEC would review a new sub-study. In the Annual review, it is stated that an ALEC sub-committee will review any applications that require NHS REC review, however the CAG Members stated that the website indicates that applications go through ALEC, unless they require a separate NHS REC review, which is the opposite of the statement in the annual review.

Condition of support change (data sources)

Despite the applicant meeting these conditions, these have raised further queries about the specific ‘s251’ support which this application has in place. It is understood that the applicant perceives the ‘s251’ support to be broadly in place for linkages, and that it does not matter which data sources the ALSPAC data is linked with. However, ‘s251’ support is specific, for specific purposes, data sources, data items and data flows. It is therefore not clear if all of the data sources that the application has undertaken linkages with, and retains, are covered by the current support. The applicant is advised to provide an amendment to CAG to cover those linkages with sources which CAG has not specifically supported, and for any future planned linkages with any new data sources, or for any change in data flows. For clarity for the CAG and for the applicant, a list is provided below of each data source, and whether or not CAG consider an amendment to be required.

1. AvonCAP - Avon Community Acquired Pneumonia (CAG reference 20/CAG/0138) – The applicant has listed this as being linked and retained under 's251', however the AvonCap study does not have specific support in place to link to ALSPAC, only to retain identifiers in order for future as yet unspecified linkages to be undertaken. ALSPAC have not submitted any specific amendment to link to AvonCap data. This data source and retention of linked data therefore requires a CAG amendment.

2. PHE/UKHSA COVID-19 - The applicant has listed this as being linked and retained under 's251', and it is thought that this is covered by an amendment supported 07 October 2020.

3. STORK Maternity – this is not listed as requiring 's251' support, and was a single extract in 1992 covered by consent as the legal basis for processing.

4. Bristol Self-Harm Register - The applicant has listed this as being linked and retained under 's251', however no records are found regarding any submitted amendment regarding linkage with this register. This data source and retention of linked data therefore requires a CAG amendment.

5. Hospital Episode Statistics (Accident & Emergency, Out Patient, Admitted Patient Care, Critical Care) from NHS Digital. CAG are comfortable that 's251' support covers this linkage, as per initial support letter.

6. Mental Health Services Data Set (comprising MHSDS, MHLDDS and MHMDS) – the CAG were satisfied that these datasets were included in ALSPAC as part of 's251' supports for various separate studies surrounding the use of mental health data, due to original CAG condition applied, for example;

a. CAG 7-06(a)/2013 – Accuracy of estimates for self-harm;

b. 14/CAG/1032 – Association between IQ and self-harm;

c. 15/CAG/0175 – Early life causes of depression and anxiety;

d. 15/CAG/0176 – Predictors, prevalence and impact of chlamydia;

e. 15/CAG/0177 – Substance use and mental health.

7. HeartSuite dataset - Source University Hospitals Bristol and Weston NHSFT (RA7) – The applicant has listed this as being linked and retained under 's251', however no records are found regarding any submitted amendment regarding linkage with this specific dataset. This data source and retention of linked data therefore requires a CAG amendment.

8. Primary Care – the applicant has stated that 's251' support is not required for this linkage as the data is anonymised prior to leaving the GP surgery. However, historically it was understood by CAG that 's251' support was required for this linkage, as per initial outcome letter, and therefore further description of this data flow should be provided to ensure that no 's251' support is required.

9. Department of Education – this is not in scope for 's251' support

Anticipated data:

10. Convictions and Cautions – Local police data - this is not in scope for 's251' support

11. Local Mental Health data from Avon and Wiltshire Mental Health Partnership NHS Trust – it was understood by CAG that these datasets were already included in ALSPAC as part of 's251' supports for various separate studies surrounding the use of mental health data, as per NHS Digital mental health data above. Please clarify if that is the case?

12. Convictions and Cautions data from Ministry of Justice (MoJ) - this is not in scope for 's251' support

Datasets thought to be included by CAG, but not listed:

13. No Welsh datasets listed as included – is this because no 's251' support required for Welsh linkage as this is undertaken by SAIL without the use of any identifiers? Other datasets not requiring 's251' have been included in the list provided by the applicant.

14. NHS Digital datasets – including birth register information, birth certificate information, marriage certificate information, death registration, cancer registration and detail from the NHS Personal Demographics Service. This was clarified in an amendment supported on 14 December 2021, after NHS Digital queried the legal basis for linkage. However, this appears not to be included in the list provided by the applicant?

Condition of support change (Annual review)

Whilst the CAG considered specifically the responses to the additional conditions, the Members also reviewed the content of the entire annual review.

Section 2 (ii): Steps taken to anonymise the information or obtain consent from individuals.

The applicant has described steps that have been taken to reduce the identifiability of the dataset. The CAG noted a comments surrounding leading a cross cohort to work with primary care software vendors (who facilitate primary care data extraction in the UK), to develop a standardised specification for extracting primary care records for longitudinal research to effectively de-identify records before the point of extraction. It is not clear if this has already been realised, hence the request for further information about the flows of GP data, to establish if 's251' support is still required for this process.

The Members queried whether it would be possible to develop any less disclosive methods of linking with HES data, for example, would it be possible to develop a split file approach, to reduce the use of 's251'? The applicant is to continue to develop further methods of reducing the identifiability of all the data flows, and report back at the next annual review.

It is also noted that 44% of the 13,238 individuals provided fair processing information have consented to the linkage/ongoing use of their ALSPAC data. In the original application, it was stated that there were around 14000 individuals in ALSPAC. Please could the applicant expand on the gap between the 13,328 individuals contacted, and the original 14000 participants? How many individuals were not contacted? Was this because no up to date contact details could be found? Were they deceased at the point of the letter campaign? Can the applicant please clarify if confidential patient information is retained about those individuals who were not contacted for consent? Is data about these individuals being linked? Is the applicant content that 's251' support is not required for the retention of any confidential patient information about those individuals, given that the consent was given by their parents at the time of birth, rather than the individual themselves?

Following on from this point, it is also noted that the original 's251' support requested by the applicant was never for retention of any confidential patient information, but was only to undertake linkages of outcome data for those patients that they could not gain consent from, and those who did not opt out. The CAG members noted that the applicants therefore are linking outcome data for 56% of the cohort (who were part of

the fair processing campaign), under ‘s251’ support. However, the applicant states that this same 56% of individuals are included into ALSPAC and identifiable information about them retained, under the original consent. This indicates that these individuals may have been initially included into ALSPAC by their parents and may not know they are included in this dataset. The CAG commented that as there was an overwhelming amount of data on these individuals, some of it very sensitive, the applicant is asked to consider whether it is reasonable to be including these patients in ALSPAC with the initial consent as the legal basis. If further ‘s251’ support is required, an amendment is required.

Section 4: Patient and public feedback

This section did not describe any updated specific patient and public involvement activities surrounding the use of confidential patient information without consent. The CAG accepted that ALSPAC has previously undertaken very good patient and public involvement, but more is required to ensure it is up to date. The CAG commented that new patient and public involvement should be undertaken to present at the next annual review, surrounding mental health, and if possible this should include those who were recently consented for linkage.

In this section, the applicant provided a link to their website. It was commented by CAG that the website was very good, but it was not immediately clear how to opt out. A new section dealing with the opt-out and explaining clearly how to access it should appear prominently on the website, to allow more simple access.

Section 5: Public benefits

This section of the annual review does not explain the public benefit of the use of ‘s251’ support. It states that outcomes are awaited, however ALSPAC has been running for 30 years, with a ‘s251’ linkage element supported for around 10 years, therefore it was not clear to the CAG why the public benefit of CAG support could not be evidenced.

Security assurance

It is a policy requirement of the Department of Health and Social Care in England that relevant entities processing confidential patient information under support maintain a satisfactory security assurance level for the duration of support, with similar arrangements in Wales. The need to maintain appropriate security assurance is a condition of support for all applications.

The current status of relevant entities processing information under support is as follows:

Due to the number of organisations involved it is the responsibility of University of Bristol, as controller, to ensure that all organisations processing confidential patient information without consent, and outside the direct care team, meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation.

This includes the following organisations;

1. The NHS Digital **21/22** DSPT review for **GP provider– EMIS Group, (Egton Medical Information Systems (EMIS) Limited YGM06)** was pending – the applicant is advised to request a review from NHS Digital as per instructions below.

2. The NHS Digital **21/22** DSPT review for **ALSPAC (University of Bristol) 8J370** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 21 October 2022)

3. The NHS Digital **21/22** DSPT review for **University of Bristol - Bristol Medical School (EE133799-BRMS)** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 21 October 2022)

4. The NHS Digital **21/22** DSPT equivalent review for **NHS Digital** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 21 October 2022)

5. The NHS Digital **21/22** DSPT equivalent review for **University Hospitals Bristol and Weston NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 21 October 2022)

6. The NHS Digital **21/22** DSPT equivalent review for **North Bristol NHS Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 21 October 2022)

7. The NHS Digital **21/22** DSPT review for **Avon and Wiltshire Mental Health Partnership NHS Trust (RVN)** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 21 October 2022)

8. A Caldicott Principles into Practice (C-PiP) outturn report for Department of Health and Care Wales (DHCW, previously NWIS) is in place.

Swansea university (UKSerP)/SAIL) DSPT not required – no confidential patient information processed without consent

Specific conditions of support (updated)

The following sets out the updated specific conditions of support applied against this application reference. The applicant is required to respond to these at the next annual review, with the exception of the amendments requested (condition 6 a), which should be processed as soon as possible.

1. Each annual review for ECC 1-05(b)/2012 will be reviewed at a full CAG meeting.

2. Updates should be provided annually regarding the number of individuals who either consent or decline to the linkage element of ALSPAC.

3. For AvonCap linkage, what proportion requires ‘s251’ support, and what proportion is processed with consent as the legal basis under common law?

4. Please confirm what proportion of sub-studies/requests for ALSPAC data the OCAP review? Especially with regards to ‘s251’ supported sub-studies?

5. Please confirm what proportion of sub-studies/requests for ALSPAC data the ALEC review? Especially with regards to ‘s251’ supported sub-studies? Does ALEC review those studies that require an NHS REC review, or does ALEC review those that do NOT require review by an NHS REC.

6. Please clarify the specific data source queries below:

a) Please provide an amendment for linkage and retention of data from AvonCap, Bristol Self-Harm Register, HeartSuite dataset, and continue to provide amendments in the future for any new specific linkages, as soon as possible.

b) Clarify the data flows for GP data to ensure no ‘s251’ support is required, and is not required, please include the removal of this ‘s251’ support in an amendment.

c) Clarify if ‘s251’ support for Local Mental Health data from Avon and Wiltshire Mental Health Partnership NHS Trust is covered by individual studies accessing mental health data.

d) Clarify if Welsh data is included in the dataset retained and clarify which legal basis this is processed with.

e) Please clarify if ‘s251’ support is required for any linkage with other NHS Digital datasets – including birth register information, birth certificate information, marriage certificate information, death registration, cancer registration and detail from the NHS Personal Demographics Service.

7. Continue to develop further methods of reducing the identifiability of all the data flows, and report back at the next annual review.

8. Please provide detail on the individuals who were not contacted for consent in the fair processing campaign? How many, for what reason, is identifiable data still retained, is their data linked. Is the applicant satisfied that no ‘s251’ support required for any part of this processing?

9. Please consider if it is reasonable to use the initial consent provided by a parent/carer to be including participants who therefore may not be aware they are in ALSPAC, into the main ALSPAC study. If further ‘s251’ support is required, an amendment is required.

10. Ongoing patient and public involvement should be undertaken to ensure the acceptability of this use of confidential patient information without consent, and presented at the next annual review, to include the use of mental health data, and to include patient participants who have recently been re-consented.

11. A new section dealing with the opt-out and explaining clearly how to access it should appear prominently on the website.

12. Please provide clearer evidence of public benefits of ‘s251’ support.

The Register of Approved Applications on the HRA website will shortly be updated to reflect the changes in the specific conditions of support.

4. Resubmitted New Applications

a. 22/CAG/0136- Flatiron Health UK Oncology Real-World Database v2.0

Purpose of application

This application from Flatiron Health UK Ltd set out the purpose of creating a research database to collect real world data (RWD) for cancer patients aged 18 years and over.

Progress in cancer treatment is dependent upon high-quality evidence to demonstrate that specific interventions are safe and effective. The gold standard for evidence development has traditionally been prospectively conducted clinical trials. For the 80% of patients not participating in clinical trials, “real world data” has the potential to contribute to understanding of what happens in routine clinical care. Also, clinical trials do not generate a diagnosis to outcome record and most often examine the impact of one line of therapy, and not the relationship between different lines of therapy. While the UK has a strong record of using real-world data and real-world evidence, the existing public and industry-funded databases have limitations that mean they are less suited for oncology observational research, drug development, HTA decision-making, clinical decision support and other high-impact uses. The Cancer Outcome and Services Data set (COSD) has been the national standard for reporting cancer in the NHS in England since January 2013, but the data quality is acknowledged to be inadequate to support clinical, academic or commercial research. The applicants seek to address these existing limitations through rapid, structured and unstructured data processing to create data for use across the oncology system.

The applicants, Flatiron Health UK, have partnered with Leeds Teaching Hospitals NHS Trust (LTHT) to create a representative, population-based cancer cohort. The database will be comprised of routinely collected retrospective data for patients aged 18 years and over who received treatment for cancer within a Flatiron Health UK partner trust. This will initially be LTHT, however, the applicants also aim to partner with 5-10 additional NHS trusts. Source data will be extracted from NHS Trust clinical systems in formats including both structured and unstructured data. This data extraction will be undertaken by members of the direct care team at LTHT. The trust will extract the relevant data and transfer the confidential patient information to a "Landing Zone" within an NHS Trust Firewall. Flatiron Health UK will access the dataset to remove the identifiers from the structured and unstructured data. The pseudonymised dataset will then be transferred to a "Joint Research Environment." There, Flatiron Health UK will undertake the initial processing and anonymise the data before transfer to the Flatiron Health UK Environment. All data processed by Flatiron Health UK after this point will be anonymised.

A recommendation for class 1, 5 and 6 support were 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	The initial cohort will be inactive and deceased patients treated within two participating Trusts, aged 18 years and over with a diagnosis of cancer. The applicants anticipate that the one-time historical data extract undertaken at LTHT will contain ~32,000 cancer patients, and about 4,000-5000 new cancer patients. The numbers will vary between trusts.
Data sources	1. Clinical information systems, including Electronic Health Records, chemotherapy ordering system, scheduling system, PACS and others, within participating Trusts
Identifiers required for linkage purposes	1. NHS Number

Identifiers required for analysis purposes	1. NHS Number 2. Hospital ID Number 3. Date of birth 4. Year of birth 5. Date of death 6. Postcode – unit level 7. Gender 8. 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 requested clarification on the potential public benefits of the study. The CAG asked that details of the research questions that the data would be used to answer were provided.

The application explained that the funds generated by use of the database would be partially used to fund the database and partially given to the NHS. The CAG requested clarification on any potential financial benefits to Flatiron from the application activity.

Scope

Flatiron Health UK's research database will include information about the following patient populations: Cancer patients newly diagnosed after pre-defined date (New patients), Cancer patients diagnosed before pre-defined date and receiving ongoing care at NHS Trust (Active patients), Cancer patients who were previously treated, but no longer actively receiving care at LTHT (Inactive patients), Cancer patients who are deceased and were previously treated by the NHS Trust (Deceased patients).

The applicants had stated that they were seeking support to include the inactive and deceased patients in the dataset, but that the new and active patients were outside the scope of support. The CAG noted that the applicants had stated that this was

because patients would be given material about the application and given the opportunity to opt-out of the use of their confidential patient information. However, opt-out was not the same as consent. The CAG agreed that consent needed to be sought from new and active patients, unless justification for not seeking consent was provided, as requested in the section below under 'Feasibility of Consent.'

Definition of the direct care team

The CAG follow guidance from the National Data Guardian, given during the Information Governance Review in 2013, which states that "direct care is provided by health and social care staff working in 'care teams', which may include doctors, nurses and a wide range of staff on regulated professional registers, including social workers...Care teams may also contain members of staff, who are not registered with a regulatory authority, but who may need access to a proportion of someone's personal data to provide care safely".

The applicants appeared to consider those employed to work in the trusts, but who were employed specifically to undertake activities related to this application, as members of the direct care team. The CAG requested clarification on the definition of 'direct care team' used by the applicants.

Third party access to the dataset

The CAG requested that details on the fees that organisations would be charged to use the data, including whether the NHS and universities would pay the same fees as commercial or private organisations that sought access to the data.

The cover letter to the CAG, provided with the application, contained the following passage, "In exceptional cases, regulators, including the US regulator the FDA, could then require access to identifiable data to carry out source document verification - that is, to validate and trace the process by which data has been transformed from its raw state into the end-product that was submitted to that regulator." The CAG requested clarification on the location of the servers used by regulatory authorities outside the UK, specifically whether the servers would be based in or outside of the UK. Clarification on whether any confidential patient information would be disclosed outside of the UK, such as to the United States Food and Drug Administration (FDA).

Use of Artificial Intelligence

The application contained references to use of artificial intelligence. The CAG requested clarification on these processes, including any natural language processors or algorithms used. The CAG requested clarity on the meaning of

‘trusted research environment’ and ‘joint research environment’ as used in the application.

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**

Flatiron Health UK’s research database will include information about the following patient populations: Cancer patients newly diagnosed after pre-defined date (New patients), Cancer patients diagnosed before pre-defined date and receiving ongoing care at NHS Trust (Active patients), Cancer patients who were previously treated, but no longer actively receiving care at LTHT (Inactive patients), and Cancer patients who are deceased and were previously treated by the NHS Trust (Deceased patients). The applicants advised that consent is not feasible for deceased patients. It was also not feasible to seek consent from inactive patients due to the potential distress this may cause.

The CAG agreed that it was not feasible to seek consent from deceased patients and those no longer in active treatment. However, as in the previous deferred outcome, no justification had been provided as to why seeking consent from patients who are newly diagnosed and/or still receiving treatment. The CAG noted that patient and public involvement had been conducted about use of an opt-out model, but a justification on why consent was not feasible had not been given. Should the applicants resubmit, a strong justification as to why consent could not be sought from this patient group needed to be given.

Use of anonymised/pseudonymised data

Confidential patient information is required to create a database of patients diagnosed with and treated for cancer, to be used to facilitate research to guide the development of new interventions, support appraisals by NICE (e.g., Cancer Drugs Fund evaluations) and other decision-making authorities to potentially accelerate access to important new therapies.

Confidential patient information is required to develop the research database. The applicant advised that data will be sourced from multiple internal systems, which do not always have robust common data linkage indexes. Patient data will be linked by the participating NHS Trusts and, in order to safely link structured and unstructured data from these sources, at least three identifiers are required.

As the identifiers vary in availability between source systems, more than three identifiers are required. The obvious direct demographic identifiers are removed,

truncated or otherwise treated to reduce the identifiability whilst maintaining the safety of linkage. The applicants noted that it will not be possible to remove all identifiers from the data transferred from the Trusts to Flatiron Health UK. The unstructured data will be processed into structured data by specialist oncology nurses and/or data professionals employed and trained by Flatiron Health UK, using Flatiron's proprietary approach and software.

It was stated in the application that the participants NHS numbers would to be deleted. CAG queried whether the research team would also delete the other items of confidential patient information held, or whether only the participants NHS number would be deleted.

'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.

Patients will be provided with information on the data that will be collected, how data is processed and used, and how this work benefits cancer patients, as well as what risks there might be, and who they can contact if they have any questions or concerns. Patients will be provided information about the National Opt-Out, and local opt-out options. The materials will be developed with Trusts, local patient representative groups and national disease-specific representation groups. The applicant advised that these materials had not yet been created. Flatiron Health UK will undertake a wide-reaching multi-channel communications programme. Advice will be sought from independent patient and public involvement and engagement specialists and their recommendations will be followed. The communications campaign will be run for 3 months, or until the participating Trust is satisfied that patients have been appropriately notified. The campaign will include; posters and leaflets displayed in waiting rooms and other high-traffic areas of the Trust, the inclusion of leaflets or description of work in patient appointment letters and other patient-facing communication, patient-tested web content on Flatiron's UK website, and on Trust websites, where agreed, and the display of electronic posters within participating Trusts. These materials had also not yet been prepared.

The applicants advised that the trusts would remove data from any patients who have registered an opt-out via local or NHS opt-out mechanisms. The National Data Opt-Out will be applied.

The CAG requested that the patient notification materials were revised into lay language and suggested that the materials were reviewed during patient and public involvement.

The CAG asked that any further patient notification materials were provided. Further details on the patient notification strategy were requested, including details on how and when the documents would be made available.

The patient notification materials needed to be revised to contain a full explanation of the planned uses of the data, including that data may be sold to third-party researchers, including commercial and private organisations.

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 have worked with their internal Patient Voices Panel, an independent DATA-CAN patient and public involvement group, and a local patient and public involvement group (in partnership with LTHT). Flatiron Health UK and LTHT have also jointly consulted with cancer patients, carers and members of the Leeds community to understand and incorporate their perspectives on the FHRD-UK.

One aspect of the applicant's patient and public involvement strategy was an initial electronic survey, in which 70% of respondents "definitely" or "potentially" supported the partnership to create the FHRD-UK. The majority of patients who responded "potentially" advised that, provided LTHT and Flatiron Health UK were open and transparent, and offer easy routes to opt out of research, patients supported this approach.

LTHT and Flatiron Health UK performed a further survey specifically related to use of an opt-out model to create the FHRD-UK. The results of this confirmed acceptability of processing identifiable patient data without consent; 95% of respondents supported the opt-out model

Since the previous CAG review, Flatiron Health UK and LTHT have received further feedback from patients and the public highlighting concerns that contacting patients would potentially cause distress. For active patients and newly diagnosed patients, the feedback received, including the opt-out survey referenced earlier, have supported the use of an opt-out model.

The CAG asked that patient and public interest groups and cancer charities were consulted as part of further patient and public involvement.

CAG noted that although 70 percent of the patient and public interest group were supportive with the partnership to create the Flatiron Health Research Database in the United Kingdom a 30 % dissatisfaction was significant. CAG asked the applicant to provide details on the objections raised.

Exit strategy

Confidential patient information will be retained in the research database, but only anonymised data will be supplied to researchers. The applicant advised that identifiers will be removed where possible before data was provided to Flatiron Health UK.

The CAG raised no concerns regarding the study's exit strategy.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Following advice from the CAG, the Health Research Authority recommended that the application was **deferred**.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised application submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Provide clarification on the potential public benefit of the study, including the specific research questions that the data would be used to answer.,

2. Consent needs to be sought from new and active patients, unless justification for not consenting these patients is provided.

3. Provide clarification on the definition of 'direct care team' used by the applicants.

4. Provide clarification on any potential financial benefits to Flatiron from the application activity.

5. Provide clarification on the fees paid to access the data by the NHS and universities compared to private organisations.

6. Clarify the proposed uses of artificial intelligence, including the processes involved, such as natural language processing and algorithms.

7. Provide clarity on the definitions of ‘trusted research environment’ and ‘joint research environment’ as used in the application.

8. Further details are required on the disclosure of confidential patient information outside the UK:
    a. Clarify where the servers used by regulatory authorities outside the UK will be located, specifically whether the servers would be based in or outside of the UK.
    b. Clarify whether any confidential patient information will be disclosed outside of the UK, such as to the United States Food and Drug Administration (FDA).

9. Clarify whether any items of confidential patient information would be held after the NHS numbers were deleted.

10. The following changes to the patient notification materials were requested:
    a. The materials need to be revised into lay language and reviewed during patient and public involvement.
    b. Any further patient notification materials to be used need to be provided.
    c. Further details on the patient notification strategy are requested, including details on how and when the documents would be made available.
    d. The patient notification materials needed to be revised to contain a full explanation of the planned uses of the data, including that data may be sold to third-party researchers, including commercial and private organisations.

11. Patient and public interest groups and cancer charities need to be consulted as part of further patient and public involvement.

12. Further details need to be provided on the objections raised by the 30% of patient and public involvement consultees who were not supportive of the use of confidential patient information as proposed within the application.

b. 22/CAG/0127 - Turning6 - A Clinical and Neurodevelopmental follow up of EPIPEG participants at 60 months

Purpose of application

This application from UCL GOS Institute of Child Health set out the purpose of medical research that seeks to investigate the association between early onset epilepsy and poor neurodevelopmental outcome. Epilepsy in the first year of life is associated with epilepsy that is difficult to treat and with poor neurodevelopmental outcomes. These can have a severe impact on the quality of life of both children and their parents, and the child's educational outcome. Little research has been undertaken into the longer-term impact of epilepsy. The applicants seek to follow-up participants from the EpiPEG study, which recruited 119 infants who had developed epilepsy within the first year of their life. The applicants propose to follow up this unique cohort of children as they reach 6 years, and will undertake comprehensive psychological assessments with the child, their parents and teachers.

The applicants will contact still living participants to seek consent to take part in the study. The original EpiPEG study was jointly undertaken by UCL GOS Institute of Child Health and Young Epilepsy (the National Centre for Young People with Epilepsy), who are joint data controllers for the EpiPEG dataset. The applicants seek support to access mortality data, provided by NHS Digital, to establish whether patients are still alive before making contact. Confidential patient information will be disclosed from the EpiPEG dataset, held at Young Epilepsy, to NHS Digital for linkage to mortality data. A linked dataset will be returned to Young Epilepsy. The parents of living patients will be contacted and invited to take part in the study.

A recommendation for class 2, 3 and 6 support were requested to cover access to the relevant unconsented activities as described in the application, which can be got from the CAT assessment form, class support requested section.

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	117 patients who were recruited into the original EpiPEG study.
Data sources	1. EpiPEG records, held at Young Epilepsy (The National Centre for Young People with Epilepsy) 2. The HES and Personal Demographics Service datasets, held at NHS Digital
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3.Date of death 4.Postcode – unit level
Identifiers required for analysis purposes	1. Date of death 2. Postcode – unit level 3. Phone number 4. Email address

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

- **Feasibility of consent**

Confidential patient information for patients who had already participated in the EpiPEG study only will be accessed. Patients will be contacted to seek consent to take part in this follow-up study. The applicants have sought advice from DARS, which advised that the consent currently in place were likely insufficient post GDPR and to seek CAG approval.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for NHS Digital to check mortality records to confirm if participants in the EpiPEG study are still alive and obtain up to date contact details so patients can be contacted to seek consent. Confidential patient information is required for NHS Digital to check mortality records to confirm if participants in the EpiPEG study are still alive.

It was stated within the protocol that the participants general practitioner would be contacted, should the participant decline participation. The CAG queried how the information would remain anonymous as the applicants would be able to link the data back to information for the specific patients in the study records.

The protocol stated that these individuals were ‘high risk’, CAG requested the applicant to clarify what was meant by this.

‘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 will only contact patients who had previously participated in the EpiPEG study. Once the applicants have verified that patients are still alive, they will contact patients by telephone, email or post to invite them to take part in the follow up study. The EPIPEG study team will send families the study introduction pack which will include a Letter of Invitation, the Patient Information Sheets (PIS), Consent Form, Assent Form,

GDPR Statement, An Expression of Interest Form and a Stamped Addressed Envelope. The existing EpiPEG study records will be checked for any evidence of existing dissent.

The CAG requested that the applicant included reference to section 251 and CAG within their initial contact. CAG noted that this contact could come as a shock to some participants. Therefore, an explanation to how their contact details were obtained could help answer some initial queries.

The CAG considered whether the National Data Opt-Out needed to be applied. Members agreed that the National Data Opt-Out did not need to be applied for the following specific reasons; the parents had given consent for the inclusion of their child's data within the last 6 years and it was reasonable to expect that they would understand that their details may still be held by the study team, and that not applying the National Data Opt-Out may mean that the applicants were unaware that patients had died, meaning that their parents may be contacted, causing distress. The CAG noted that this decision did not set a precedent for other applications.

CAG requested that when consent was sought for the follow-up that it included consent for further data linkages and uses, to avoid the need to submit further CAG applications.

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.

No patient and public involvement has been undertaken. The applicants had decided, following the REC review of the application, that it is in the patients' best interests to verify whether the child participant is still living before making contact to seek consent to take part in the follow-up study.

The CAG agreed that patient and public involvement did not need to be carried out, as this would be disproportionate to the scale of the breach in the common law duty of confidentiality involved.

Exit strategy

Patients will be contacted to seek consent to participation in the follow-up study.

CAG was content with the exit strategy used.

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. Clarification needs to be provided on how the information provided by patients GPs would remain anonymous as the applicants would be able to link the data back to information for the specific patients in the study records.

2. Clarify the meaning of ‘high risk’ as stated in the protocol.

3. The materials used to reconsent patients need to cover further data linkages.

4. The materials used to contact patients need to explain the role of the CAG and section 251.

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. Favourable opinion from a Research Ethics Committee. **Confirmed 19 May 2022.**

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/Pending:

   The NHS Digital 21/22 DSPT review for organisation ‘**NHS Digital’** was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 26/09/2022).

The NHS Digital 21/22 DSPT review for organisation '**Young Epilepsy (the National Centre for Young People with Epilepsy)**' was confirmed as 'Pending' on the NHS Digital DSPT Tracker (checked 26/09/2022)

5. New Applications

a. 22/CAG/0124 - Artificial Intelligence in Mammography Study (AIMS) Part C: Feasibility of an artificial intelligence system to improve the quality and efficiency of breast cancer screening

Context

Purpose of application

This research application from Imperial College London set out the purpose of medical research which aims to test the ability for the integrated system to correctly perform eligibility checks and provide Artificial Intelligence (AI) results only for women who are eligible, within the breast screening programme, explicitly avoiding any potential for AI outputs to influence patient care, as part of a prospective observational feasibility study.

1 in 8 women will be diagnosed with breast cancer in their lifetime. The UK National Breast Screening Service (NBSS) is proven to detect breast cancer early where treatment is more successful, using 2 expert readers (radiologists and radiographers) to assess each mammogram (x-ray of the breast), with disagreements decided with the help of an additional 2 readers. However, a radiologist workforce crisis threatens the screening programme's long-term sustainability. AI has been shown to be as good as two expert UK Radiologists at detecting and excluding breast cancer in an experimental setting. Google Health's AI system identified cancer in mammograms with greater accuracy than specialists. This study aims to test the AI system running 'silently' within breast screening clinics at two NHS sites, to provide the necessary evidence to form the basis for a proposed deployment framework to support progression to future interventional use in a way that delivers measurable benefits to public health.

Imperial College Healthcare NHS Trust and St George's University Hospitals NHS Foundation Trust are the 2 participating sites. The AI system will be applied to all screening clinics at each site for the study. Cases for inclusion in the feasibility study are identified through querying the screening clinics recorded on the National Breast

Screening Service (NBSS) database at each local site following clinic completion. The Royal Surrey NHS Foundation Trust (RSNFT) Secure Medical image Anonymisation for Research Trials (SMART) box (a piece of software) has already been installed at the NHS sites for the purpose of data collection from the breast screening programme for several ethically approved projects. The SMART box queries NBSS and PACS and carries out the de-identification process to pseudonymise the clinical data and imaging data used for the study. This process is automated and does not need any human intervention and will exclude patients that opt-out. The associated images are retrieved from the site's mammography PACS. The images are then pseudonymised and all identifiable DICOM tags are stripped or replaced with pseudonyms where necessary. Clinics will run routinely with no change to existing practises. Pseudonymised images are transmitted to the pseudonymised data Cloud store, hosted in the Google Cloud Platform environment. As a proof-of-concept, some images will be re-identified at the Trusts, and only direct care team will have access to any confidential patient information.

All patients whose images are read by the AI will be further followed up for a period of 3 months. This will enable collection of data such as arbitration outcomes and assessment outcomes should the patient be recalled for further investigation. Diagnosis outcomes will provide an estimate of the sensitivity and specificity of the AI system for patients that were recalled to the clinic. 3 months after the screening appointment has been attended , this data will be collected by NBSS and linked to the pseudonymised patient record on the Trust's research server.

Despite the processes being as automated as possible, and no confidential patient leaving the Trusts, 's251' support is being sought in this case, for the potential for SMARTbox technicians employed by Royal Surrey, who are not considered members of the direct care team, to occasionally have to view confidential patient information whilst carrying out technical support.

A recommendation for class 1 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	Women undergoing routine breast cancer screening (age 50–70), as part of the national breast screening programme at Imperial College Healthcare NHS Trust and St George's University Hospital NHS Foundation Trust between the study dates. - Mammography images acquired using Hologic/Lorad, Siemens, or GE devices

	Approximately 14000
Data sources	1. Screening clinics recorded via the National Breast Screening Service (NBSS) database at each participating site 2. Images from each participating site mammography PACS
Identifiers required for linkage purposes	1. Name 2. NHS number
Identifiers required for analysis purposes	1. Gender 2. Ethnicity 3. Age Therefore, analysis will be undertaken on an effectively anonymous dataset

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 very important and 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 has reasoned that given COVID-19 backlogs, reluctance to disrupt patient flow, logistical difficulties with screening vans, and administrative complexity with appointments being made centrally with little flexibility, there will not be an opportunity for the direct care team to actively ask for informed consent. Through the

opt-out model, the study also will more closely resemble real world conditions and include a non-biased and representative population within these real-world NHS settings. This model was also support by patient and public involvement. CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is only being used at the point of pseudonymisation, and then re-identification in order to feed the results of the AI back. It is not required for analysis and is anonymised at the earliest opportunity. CAG was content that using anonymous information was not a practicable alternative.

'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.

Women attending during the study periods will be provided with a short information leaflet about the research in the post alongside their appointment confirmation letter (This contact is from the direct care team, so no 's251' support required for this contact). The leaflet will clearly outline details of how to opt-out should they wish.

Detailed patient information leaflets will be available online. The short information sheet received in the post will also be available at the screening sites and will also be available in several languages (to be translated after approval from the ethics committee). A poster to be displayed at the sites has also been provided. There is a study specific opt out. The national data opt out will be applied.

The CAG was content with the notification and opt out methodology, and with most of the content of the documentation. However, Members requested for all participant facing documentation to include a description on the breach of confidentiality for which 'section 251' support was applied for, to try to explain this processing to patients. This description should include the role of CAG and the fact that the applicant has 's251' support to cover this possibility of a breach of confidentiality. The CAG noted that this is also likely to reassure patients that appropriate safeguards are in place regarding their data.

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.

Applicants run patient and public involvement groups of up to 14 participants, who have experienced breast cancer previously or have undergone mammography. This included 5 sessions in 2021 and 3 sessions in 2022, each session being 2 hours in length. These have been on various themes. Surveys and questionnaires have also been undertaken. 2 lay partners have joined the steering committee.

12 participants attended a remote 2-hour patient and public involvement session in July 2021 which focussed on any issues surrounding patient consent when artificial intelligence applications are used in mammographic breast screening. There was support for the study design - the majority of participants were in favour of a public or site-specific notification approach, with participants expressing if they wish to opt-out.

The patient and public involvement group has also been involved in creating the participant information leaflet and the study explainer video.

CAG stated that they were satisfied with the Patient and Public Involvement and Engagement undertaken for the study.

Exit strategy

Exit strategy will be the ceasing of SMARTbox activity for this application, as the individuals who may need to access the SMARTbox for maintenance purposes will then no longer have access.

The main feasibility study will run for a minimum of 4 weeks and a maximum of 8 weeks.

Extraction of 3 month follow up data also requires ‘s251’ support, and this will be undertaken 3 months after each woman has attended for their screening visit.

It is difficult to estimate when this will be exactly, until the study begins.

CAG noted that they were content with the exit strategy.

Commendation

CAG would like to commend the applicant on the quality of the final set of documentation submitted, and the clarity of the eventual application.

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. Please update patient facing materials to explain why 's251' support is in place, as per the advice in this letter, and return to CAG for review within one month from the date of this letter

2. Favourable opinion from a Research Ethics Committee. **Confirmed 22 September 2022.**

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 **21/22** DSPT reviews for '**St. George's NHS Foundation Trust'** and **'Imperial College Healthcare NHS Trust'** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 26 September 2022).

6. Ratification of Application

a. 22/CAG/0120 - A Retrospective Follow-up of Two Services for High Risk Offenders with Personality Disorder

This application was reviewed at the 08 September 2022 Full CAG meeting. However, as the meeting was not quorate for this discussion, the application was rediscussed on 22 September 2022 and members ratified the decision made at the previous meeting.

Purpose of application

This application from the East London NHS Foundation Trust set out the purpose of medical research that seeks to evaluate re-offending and psychosocial wellbeing outcomes after interventions provided by two Offender Personality Disorder (OPD) Pathway programmes.

Personality disorders (PDs) are a group of mental health disorders that are characterised by inflexible, maladaptive patterns of behaviour, emotional expression,

and cognition. These patterns are long-standing and affect a range of personal and social situations. The Offender Personality Disorder (OPD) Pathway programme is a jointly commissioned initiative between NHS England and Her Majesty's Prison & Probation Service. It encompasses psychologically informed services for offenders who are likely to have a PD. These treatment services are set in prisons, secure hospitals, and community settings, and all aim to reduce repeat offending and improve psychological wellbeing. There is limited evidence that various treatments have a positive impact of recidivism rates and psychological behaviours and behavioural outcomes among personality disordered offenders, however few follow-up studies have been undertaken. The applicants are seeking to examine the long-term psychosocial and reoffending outcomes, and the impact of services on sentence progression, for all men who have passed through two OPD Pathway services since they opened; a Psychologically Informed

Planned Environment (PIPE) at HMP Swaleside and an adapted therapeutic community model run by the Millfields Unit. Data will be gathered from existing service, prison, probation and police records. The results could help to inform the future development and improvement of similar services, in order to improve the availability and effectiveness of services supporting offenders with PD.

Research teams at Millfields Unit and Swaleside will identify suitable patients from their local records. At the Millfields Unit, patient names and dates of birth will be transferred to a password-protected database and assigned unique study IDs. This database, which will include confidential patient information and the unique study IDs will be transferred to HMP Swaleside via encrypted email.

A recommendation for class 1, 2, 4, 5 and 6 support were 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	All men who have ever been admitted to and discharged from the Millfields Unit between 01 January 2005 – 31 December 2021 or the PIPE at HMP Swaleside between 01 January 2014 – 31 December 2021. For the control group, men who were referred to the PIPE, but not admitted, between 01 January 2014 – 31 January 2019 are eligible for inclusion. 150 patients will be included in the control group.

	Approximately 80 patients will be recruited from Millfields Unit
Data sources	1. Patient records at the Millfields Unit (East London NHS Trust)
Identifiers required for linkage purposes	1. Name 2. Date of birth
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Prison/hospital security level 4. Accommodation type 5. Gender 6. Occupation 7. 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 requested further clarification on the purpose of the application and whether the study would be used to improve the care of patients, or whether the results would be used to inform how the units are run.

Scope

The CAG requested clarify on the scope of support sought. The remit of s251 applies to confidential patient information, as defined in s251 of the NHS Act 2006. In short, this covers patient information generated in circumstances leading to an obligation of confidence. The CAG was satisfied that data from the Police National Computer, probation records and prison records were outside s251, the remit does extend to prisoner health records, whether these were generated by the NHS or another healthcare organisation providing the care and treatment of prisoners.

The applicants had indicated that patient records at the Millfields Unit were under the scope of support, while records from the Swaleside Unit were outside the scope of support.

The CAG requested that the applicants confirm that the records held by HMP Swaleside that would be processed for this application were not health records.

The applicants had agreed that the National Data Opt-Out would be applied to patient records at Millfields. Patient records would also be checked for evidence of existing dissent to use of their data in research.

If any of the data provided by HMP Swaleside is determined to be confidential patient information, then the National Data Opt-Out will need to be applied to this cohort. A local dissent mechanism, including checking of records for evidence of existing dissent to use of their data in research, will need to be implemented.

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**

In the study protocol, the applicants cited the sample size as a reason for not seeking consent. However, approximately 330 patients would be recruited, which is a relatively small cohort. The applicants had cited a low and potentially biased response rate, which the CAG agreed is a stronger reason for not seeking consent. Former patients may be difficult to locate and unlikely to give informed consent.

CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link patients across several datasets and organisations.

CAG was content that use of anonymous information was not a practicable alternative.

'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 notice, (document - Participant information), about the study will be placed on the East London NHS Foundation Trust, Millfields Unit and London Pathways Partnership (LPP) websites. This notice will include details on the purpose of the study, the data used and how it will be stored. Email and postal details were provided for participants who wish to ask further questions or to dissent from data collection. A telephone number for the Swaleside was also included.

In response to suggestions from a focus group with current Millfields patients, information about the study will also be shared with commissioners and will be added to the Millfields Unit microsite once this has been developed.

Any participants who choose to opt-out from data collection will be removed from the study and any research data collected up to that point will also be destroyed. The applicants had agreed that the National Data Opt-Out would be applied to patient records at Millfields. Patient records would also be checked for evidence of existing dissent to use of their data in research.

If any of the data provided by HMP Swaleside is determined to be confidential patient information, then the National Data Opt-Out will need to be applied to this cohort. A local dissent mechanism, including checking of records for evidence of existing dissent to use of their data in research, will need to be implemented.

The CAG noted that not all of the target population would have access to a computer and/or the internet and queried whether posters could be used to promote the study as well as online information. If this approach is not feasible, justification as to why needs to be provided.

The CAG noted that the prison population tended to have a lower reading age than the general population and asked that the patient notification materials were reviewed with help from a Patient and Public Involvement group.

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 CAG asked that the patient notification materials were reviewed with help from a relevant Patient and Public Involvement Group.

Exit strategy

All identifiable data, including confidential patient information, will be pseudonymised at the point of extraction. All participants will be given a unique, numeric study ID. Upon extraction of data from patient records, this information will be allocated to the study IDs so that the final research dataset will not contain identifiable data. The pseudonymised data and identifiers will be held in separate password-protected databases. It is estimated that data collection will be complete within 2.5 years and all data will be pseudonymised by this point. The names used for data linkage will then be destroyed. The applicants advised that precise dates of birth are required so they can be passed on to HMP Swaleside to identify the same participants for follow-up. Once they have been identified in prison/probation systems, dates of birth can be converted to age and dates of birth removed. Since date of death is not needed to be passed on to Swaleside, this can be converted to age at death upon data extraction.

CAG was content with the exit strategy.

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. Provide further clarification on the purpose of the application and whether the study will be used to improve the care of patients, or whether the results will be used to inform how the units are run.

2. The CAG requested that the applicants confirm that the records held by HMP Swaleside that would be processed for this application were not health records.

3. If the data held by HMP Swaleside is confidential patient information and will be processed under s251 support, then confirmation needs to be provided that the National Data Opt-Out will be applied, as well as a local dissent mechanism.

4. Use of posters, as well as online information, needs to be considered. If this approach is not feasible, justification as to why needs to be provided.

5. The wording of the online information and any other patient notification materials, such as posters, need to be reviewed by a relevant Patient and Public Involvement group.

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. 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. **Pending:**

   The NHS Digital 21/22 DSPT reviews East London NHS Foundation Trust**,** HMP Swaleside (Ministry of Justice), were pending NHS Digital review.

7. Any other business

- The Chair informed CAG that the Chairs report would be shared with them in the coming week.

- The Chair informed CAG of a joint meeting being held with the National Data Gaudian in October to discuss CAG's role.

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

Signed – Chair	Date
Ms Clare Sanderson, CAG Alternate Vice Chair *Dr Tony Calland, MBE, CAG Chair*	*06 October 2022* *02 October 2022*

Signed – Confidentiality Advice Team	Date
William Lyse, HRA Approvals Administrator	*01 November 2022*