Health Research Authority

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

August 2021

1. New Applications

a. 21/CAG/0074 - CQC 2021 Community Mental Health Survey - Mixed Methods stand alone pilot

Name	Capacity
Dr Patrick Coyle	CAG vice-chair
Professor Barry Evans	CAG member
Dr Liliane Field	CAG member
Dr Rachel Knowles	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Pauline Lyseight-jones	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Professor Sara Randall	CAG member
Mr Dan Roulstone	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This non-research application submitted by Ipsos MORI on behalf of the Care Quality Commission, set out the purpose of administering the 2021 Community Mental Health Survey - Mixed Methods stand alone pilot. The community mental health mainstage survey has previously been conducted using a postal approach. However, this pilot study will test the effectiveness of a mixed methods approach, offering the questionnaire online (in addition to a postal survey), and sending SMS reminders (in addition to postal reminders).

The community mental health Survey falls within the NHS Patient Survey Programme (NPSP). The NPSP was initiated in 2002 by the then Department of Health, and is now overseen by the Care Quality Commission (CQC), the independent regulator of health and social care in England.

Ipsos MORI will select 21 Trusts for inclusion in the pilot with the aim of 20 trusts completing it. Trusts will collect information of all eligible patients and, following suitability checks, will share confidential patient information with the coordination centre (IPSOS MORI). The sample for each trust will be split into a “control” group and an “intervention” group. The “control” group will receive the survey as they would for the current Community Mental Health Survey design (a paper questionnaire only). Those in the “intervention” group will receive a different mailing strategy designed to encourage them to take part online – this will also include SMS messages. A postal questionnaire will be available to all patients. All fieldwork will be conducted by the Coordination Centre for Mixed Methods (based at Ipsos MORI). This differs to the main survey where NHS trusts may opt to undertake the mailing of questionnaires themselves or to employ an approved survey contractor to administer the survey on their behalf.

IPSOS MORI will distribute questionnaires to patients using the approach detailed below;

The intervention group will receive;

Contact 1: Letter + URL link for online questionnaire

Contact 2: SMS despatched 7 days later +URL link for online questionnaire

Contact 3: Contact 1 +2wks, 50% letter +URL, 50% letter +URL +paper questionnaire

Contact 4: SMS despatched 7 days later +URL link for online questionnaire

Contact 5: Contact 3 +2wks, letter with paper questionnaire (no URL)

The control group will receive the same number and style of contacts as the 2021 Community Mental Health Survey approach:

Contact 1: Letter with paper questionnaire

Contact 2: 1 week after contact 1, reminder letter

Contact 3: 2 weeks after contact 2, reminder letter with paper questionnaire

Ahead of each reminder, it will be necessary to remove all respondents who have completed the survey already, and to conduct a DBS or local check on the full sample. If anyone has requested to be opted out of further reminders, they should also be removed at these timepoints.

A recommendation for class 5 & 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	Patients aged 18 and over who had been in contact with NHS mental health services in the three-month period from 1st May 2021– 31st July 2021, and who were receiving specialist care or treatment for a mental health condition, including those who receive care under the Care Programme Approach (CPA) • Who were seen by someone face-to-face at the trust or via video conference (e.g. using Attend Anywhere, MS Teams, Zoom etc) or telephone call between 1st May and 31st July 2021 (the sample period); **AND** • had at least one other contact (face-to-face, video conference, phone or email) either before, during or after the sampling period 760 service users from 20 Trusts. (a total of 14,000)
Data sources	1. Electronic patient records, Mental Health Trusts in England

Identifiers required for contact purposes	1. Trust code 2. A standardised unique identifier code, 3. Title (Mr, Mrs, Ms, etc.) 4. First name 5. Surname 6. Address Fields 7. Postcode 8. Mobile phone number where available
Identifiers required for analysis purposes	1. Trust code 2. The unique identifier code (as above) 3. Year of birth 4. Postcode 5. Gender 6. Ethnic category 7. Day of last contact 8. Month of last contact 9. Year of last contact 10. CPA status 11. CCG code 12. Mental Health Care Cluster Codes 13. Mode of contact since 1st March 2020 14. Postcode (mapped to Lower Layer Super Output Areas to allow analysis by deprivation and region, then securely deleted)

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Please provide evidence of NHS Digital review of the DSPT for Ipsos MORI (standard condition of support, below).**

NHS Digital emailed this to the CAG inbox on 4th August 2021. This satisfies the standard condition of support.

Response to applied condition

This letter summarises the applicant response to the condition applied in the provisional support letter. The applicant response was considered by a sub-committee of the CAG.

1. **Please provide assurance to CAG of the process that would be followed should a Trust send confidential patient information to Picker in error, and that participating trusts were aware of this process, within one month from the date support provided.**

The applicant provided a response to the condition on 2nd July 2021, in advance of the DSPT being in place. They provided a detailed response to describe the process. If a trust mistakenly sends a sample file containing patient-identifiable data to the Coordination Centre for Existing Methods based at Picker, the Coordination Centre for Mixed Methods (based at Ipsos MORI) is obliged to report this to the Care Quality Commission (CQC). The CAG will be notified by the CQC. Applicants will advise Picker to delete the sample file immediately. The Trust will be advised to consider logging the incident as a serious incident on the Data Security and Protection Toolkit.

The Survey Handbook and Sampling Instructions specify that, "Trusts must not send patient identifiable data, such as patient names and/or addresses to the Coordination Centre for Existing Methods based at Picker or any of the approved contractors, as they are not involved in this pilot" and the Sample Declaration Form makes clear the consequences of mistakenly sending patient-identifiable data to Picker. Webinars with the Trusts are run by applicants in advance of sample submission, which will reiterate the importance of sharing the sample with the Coordination Centre for Mixed Methods (based at Ipsos MORI) and not Picker.

Prior to submitting samples, the Sample Declaration Form must be reviewed and signed-off by trusts' Caldicott Guardians. Applicants will check these forms are completed satisfactorily before issuing Trusts with a secure transfer link, limiting the risk that the sample is sent elsewhere in error.

The Members were content with the response provided and recommended full 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 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. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved

the ‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information. **Confirmed:**

The NHS Digital **20/21** DSPT review for **Ipsos MORI** was confirmed as ‘Standards Met’ (by email to the CAG inbox 4 August 2021).

b. 21/CAG/0020 - The effect of age at first invitation for breast screening in the NHS Breast Screening Programme in England and Wales (AFBSS)

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Mr David Evans	CAG member
Dr Liliane Field	CAG member
Professor Lorna Fraser	CAG member
Dr Katie Harron	CAG member
Dr Simon Kolstoe	CAG member
Ms Diana Robbins	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from University of Oxford set out the purpose of medical research which aims to establish whether the age at women are first invited for routine mammogram affects mortality from breast cancer. NHS Digital will link further death records and cancer registrations to flagged Age at first breast screening (ABFSS) patients originally flagged on the NHS Central Register (NHSCR), and supply the outcomes to the applicants who will link these data to the dataset they already hold on 1.4 million women born in 1945-1948 in England and Wales.

This was previously supported as a non-research application in 2007; PIAG 3-05(l)/2007, however in 2018, the NHS Breast Screening Programme changed their definition of age, meaning PIAG 3-05(l)/2007 can no longer be classed as an audit of its routine practices. Therefore applicants are seeking support for this new research application to complete data analyses and to extend follow up period to include data from between 31st December 2012 and 31st December 2019 for research purposes, and replace the previous PIAG application.

In England and Wales, the NHS routinely offers breast screening every three years to all women aged 50-70 and this screening has been shown to reduce mortality from breast cancer. Although women are eligible for breast screening at the age of 50 years, in practice they are first invited for screening between the ages of 50 years and 52 years. It is not known whether this three-year range in age makes a difference to breast cancer mortality. The study aims to address this, and findings will inform screening policy and practice regarding the age at first routine mammogram.

A part of PIAG 3-05(l)/2007, data routinely collected by the NHS Breast Screening Programme on women's first invitation to routine screening were extracted from the NHAIS system in England for women born in 1945-1948. These women were flagged on the NHSCR, which enabled follow up for cause-specific mortality and cancer diagnosis up to 31st December 2012, through record linkage to death records and cancer registrations. Details of individuals in the study population have already been collected and are held securely at the University of Oxford. This database contains identifiers: name, NHS number, date of birth, postcode and a unique participant study number only.

The study population of AFBSS patients are already flagged on the NHSCR, held by NHS Digital. The same function is now carried out by the Personal Demographics Service (PDS), but as the women in the study were flagged on the NHSCR, NHS Digital will be able to trace their details using the unique participant number. Support is requested for NHS Digital to link the flagged patients to further death records and cancer registrations from the ONS Civil Registration Mortality dataset, and Cancer Registrations Data dataset controlled by Public Health England, until 31st December 2019. These datasets are also held by NHS Digital. Deaths, cause of death and cancer incidence will be provided from NHS Digital to the applicants at University of Oxford alongside a unique study number. This data flow also requires support as date of death

can be considered an identifier. The applicants will then link the provided outcome information to their existing dataset using the unique participant study number. The data will be pseudonymised for analysis, except full date of death which is required. Name, NHS number, date of birth, postcode will be deleted before linkage takes place, as soon as the applicants can access the historical database. Once the study is published all identifiable data will be destroyed, and the applicants estimate that support will be required until 31st December 2024.

A recommendation for class 1, 2, 4 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	1.4 million women born in 1945-1948 in England and Wales who were alive, on the NHAIS system; and age 50 in 1995-1998 This application is only concerned with linkages to death and cancer outcomes between 31sT December 2012 and 31st December 2019
Data sources	2. PIAG 3-05(l)/2007 dataset, held at the University of Oxford. Data collected under Regulation 5 support. 3. NHS Digital - ONS Civil Registration Mortality dataset, and Cancer Registrations Data dataset (controlled by Public Health England, but held by NHS Digital), and details of previously flagged ABFSS patients on the NHS Central Register (NHSCR).
Identifiers required for linkage purposes	1. Unique participant study number only
Identifiers required for analysis purposes	15. Full date of death 16. date of birth modified to month and year of birth

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Please provide confirmation that identifiers are currently retained within the PIAG 3-05(I)/2007 dataset, within three months from the date of this letter.**

The applicants confirmed that they are unable to confirm that identifiers are currently retained, as the University Information Governance Team has advised that the PIAG 3-05(I)/2007 dataset must remain inaccessible to researchers until CAG support is in place. However, the annual reviews for PIAG 3-05(I)/2007 report that the identifiers were retained. The Members were content with this response.

2. **The exit strategy from support for PIAG 3-05(I)/2007 was to anonymise the data after the linkage and prior to analysis. At the time point of 'freezing' follow up in 2016, it is not clear why identifiers were still retained at this point instead of anonymising. Can you please clarify why identifiers were retained, within three months from the date of this letter.**

The applicant confirmed that the identifiers were retained to allow for linkage checking of follow-up data, however, the applicant for 21/CAG/0020 was not the same for PIAG 3-05(I)/2007 so it cannot be stated with certainty why the agreed exit strategy was not followed. The CAG were content with this response.

3. **Please explain why retained identifiers need to be processed at all by the applicant, and consider if the study could merely rely on the Unique participant study number allocated by NHS Digital for linkage, within three months from the date of this letter.**

Upon further consideration, the applicants agree that the study can rely on the unique participant study number allocated by NHS Digital for linkage as the study population's records can be accurately traced through the NHS Digital Master Person Service. Date of death will still be retained for analysis purposes. The Committee were pleased with this development and felt more comfortable that further identifiers were not required for linkage.

4. **Please consider, if they are required, whether identifiers can be deleted after linkage and prior to analysis. If identifiers are to be retained, further justification is required for the ongoing retention of identifiers until after analysis and publication, within three months from the date of this letter.**

As the applicants now plan to rely on the unique participant code for linkage, the identifiers (except for date of death which will be retained for analysis purposes) will be deleted as soon as the applicants are able to access the PIAG 3-05(l)/2007 data. The CAG were content with this response.

5. **Please provide the CAG with details of other secondary research questions which may be answered using this dataset, in order to persuade the CAG of the research being in the public interest, within three months from the date of this letter.**

The applicant reasons that data from other countries are unlikely to be relevant to questions about the UK population, due to the use of different screening modalities and different time intervals between invitations to screening. However, the applicant has developed some secondary research:

1) Does breast cancer mortality vary by region?
2) Does the effect of age at first invitation on breast cancer mortality vary by region?
3) Does the effect of age at first invitation on breast cancer mortality vary by time period (0-4, 5-9, 10-14, etc. years after a woman first becomes eligible for screening)?

The CAG were content with these, and noted that a protocol amendment will be submitted to the Research Ethics Committee regarding these. This letter can be taken as 's251' support in the context of the inclusion of these additional research questions, and no further amendment is required to CAG.

6. **Please consider shortening the patient notification text for the website, and discuss the notification methods with patients and the public for feedback on these materials, and provide updated documentation to the CAG within three months from the date of this letter.**

The applicants provided a revised version of the patient notification text for the website, which has been shortened and modified in accordance with feedback we received from patients and the public. A revised version of the privacy notice has also been provided, which is referred to in the patient notification text and has been modified to reflect the

fact that the study will no longer retain identifiers other than date of death. The Members were content with this response.

7. **Please ensure that an email and telephone number are included alongside a postal address on the patient notification text for the website in order for people to opt out if they wish, and provide updated documentation to the CAG within three months from the date of this letter.**

This has been included as part of the updated notification, and the CAG were content with the response.

8. **Please consider if it is necessary to ask for an NHS number in order to process an opt out request. If It is, please update the patient facing documentation in order to guide people in how they can find out this information. Please provide updated documentation to the CAG within three months from the date of this letter.**

The applicants do require NHS number for opt outs in order to establish accurately who is opting out. The documentation has been updated with how patients can find this information. The Members were content with this response.

9. **Please provide a Patient and Public Involvement plan, which includes feedback regarding the acceptability of the use of confidential patient information without consent for the purposes of the study, within three months from the date of this letter.**

The applicants provided a Patient and Public Involvement plan, including feedback regarding the acceptability of the use of confidential patient information without consent as well as feedback regarding the patient notification text for the study website. The Committee accepted this plan.

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 under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 for **PIAG 3-05(l)/2007** will be expired from the date of this letter, and replaced by **21/CAG/0020**.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 12 February 2021**

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

   The NHS Digital **20/21** DSPT reviews for **University of Oxford - Medical Sciences Division - Nuffield Department of Population Health (**EE133863-MSD-NDOPH-NDPH), and the **20/21** DSPT equivalent for **NHS Digital** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 10 August 2021)

c. 21/CAG/0043 - Barts Cancer Institute Breast BioBank

Name	**Capacity**
Mr David Evans	CAG member
Ms Sophie Brannan	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Barts Cancer Institute, Queen Mary University of London set out the purpose of medical research that aims to provide support for Barts Cancer Institute Breast Biobank (BCIBB) staff, who are not members of the direct care team to identify and screen patients attending Barts Health NHS Trust for a breast procedure (which covers patients from Barts, Whipps Cross, Homerton and Newham Hospitals) for eligibility, in order to subsequently seek their consent into the Barts Cancer Institute Breast BioBank. The aim of the Biobank is to recruit patients and healthy volunteers, and to collect, store and share high quality tissue and biological samples with associated data for translational research into breast cancer; however all other processes of the Barts Cancer Institute Breast BioBank do not require Regulation 5 support, as all participants are consented. The BioBank is co-funded by Breast Cancer Now and Barts Cancer Institute, and has been recruiting patients since 2015. The Barts Cancer Institute Breast Biobank (BCIBB) is also the parent site of the Breast Cancer Now Tissue Bank (BCNTB) and will donate equal samples into the BCNTB. The current model is for the direct care team to identify and consent eligible patients, but the applicants have identified that this model is not practicable as the process is very inefficient. The direct care team is not able to spend time identifying and introducing the patients to the BCIBB team during very busy clinic hours and consequently the number of identified patients is currently very low.

Breast cancer is the second most common cancer in women in the Western world. A woman in the UK born after 1960 has a 1 in 7 lifetime risk of developing breast cancer, and whilst overall survival has significantly improved, there are still ~10,700 annual deaths from breast cancer. There is therefore a continued need to better understand the disease, the mechanisms underlying it and its response and resistance to treatment. Understanding normal breast cell biology is also critical to understanding the development of breast cancer as well as improving approaches to prevention, and therefore applicants also will approach healthy controls for consent.

Members of the BCIBB team will use records of planned surgeries provided by the Direct Care team (e.g. surgical calendar, Surginet, Multi-Disciplinary Meetings (MDTs), Pre-assessment clinic lists, all of which can be accessed via Electronic patient records (EPR)) to identify patients that may be appropriate to approach for consent. The BCIBB staff already have access to the Barts Health NHS Trust clinical systems in order to collect information about consented biobank patients, via a designated Barts Health NHS Trust PC installed in Barts Cancer Institute, Queen Mary University of London. The BCIBB staff will access this Barts Heath NHS Trust PC in order to access EPR and retrieve the clinical lists of anybody attending for a breast related procedure. The list of eligible patients will be checked weekly to remove any patient who has opted out via

the national data opt out. This process is still in development but will be implemented by September 2021. The clinical lists will be saved on this computer (within the Barts health NHS Trusts servers) and BCIBB staff will then use various electronic patient records in order to screen any patients who have not opted out via national data opt out for eligibility, including EPR, Care Record Service (CRS)/Millennium Powerchart. In order to undertake this task they will view confidential patient information (Full name, NHS Number, Hospital number, Date of birth) of all patients that are attending for a breast related procedure within Barts Health NHS Trust, and this is why support is requested. BCIBB staff will record if a patient is eligible or not on the clinic lists, and also on the shared calendar of the BCIBB shared NHS.net email address on the Barts NHS Trust servers. This will enable the members of the BioBank to know whether a patient needs to be approached prior to surgery to request consent.

The BCIBB team member will use the shared calendar entries, and the screened electronic clinical list to approach the direct care team and ask whether it is appropriate to approach the identified patient for BCIBB consent. Providing the direct care team are happy that it is appropriate to consent the patient for research purposes the BCIBB team member will approach potential patients in order to gain consent. Patient consent or dissent to the Tissue Bank will continue to be recorded on the patient's record on Millennium Powerchart to prevent a dissented patient being inadvertently re-approached. However, the identifiable details of any patient that dissents will not be recorded or stored in the BioBank systems. The electronic version of the screening list containing identifiers will be kept on Barts Health NHS Trust server, and will be deleted once the patients have consented (or dissented). Any hard copies will be destroyed through confidential waste or shredded, although the applicant has confirmed there should not be any paper copies.

A recommendation for class 1, 3 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	All patients that are attending for a breast related procedure within Barts Health NHS Trust Approximately 5000 patients per year.

Data sources	Barts Health NHS trust: Electronic Patients Record (EPR) and Care Record Service (CRS)/Millennium Powerchart (this includes records of planned procedures produced by the Direct Care Team (e.g. surgical calendar, Surginet, Multi-Disciplinary Meetings (MDTs), Pre-assessment clinic lists)
Identifiers required for identification of cohort	9. Full name 10. NHS Number 11. Hospital number 12. Date of birth
Identifiers required for analysis purposes	17. N/A – undertaken with consent

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Please provide the Caldicott guardian letter of support.**

This letter was provided as a response to provisional outcome, and was accepted by the CAG Sub-Committee.

2. **The clinical information letter needs to be revised as follows:**

    a. **It needs to be made clear that the eligibility screening will be undertaken by staff who are not members of the direct care team.**

    b. **The letter needs to signpost patients to further details about the biobank, including a link to the BCN website.**

    c. **The use of the National Data Opt-Out and the local opt-out mechanism needs to be explained.**

d. **The opt-out information also needs to include a telephone contact as well as email.**

The applicant provided the revised clinic letter based on the points detailed above on 29 July 2021. The CAG were broadly content with the response, however they requested two small amendments to be made before recommending support, including stating a few of the data items required to undertake screening, and to ensure that the local opt out option was sufficiently clear. The applicant updated the response and provided further information on 11 August 2021, which was accepted.

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 provided for 5 years, to be in line with the REC – at this point a duration amendment should be submitted for continued support.

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

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

   The NHS Digital **2019/20** DSPT review for **Barts Health NHS Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (11 August 2021).

d. 21/CAG/0108 - What clinical outcomes are associated with the 'joint care' for teenagers and young adults with cancer? Short title: BRIGHTLIGHT_2021

Name	Capacity
Professor Barry Evans	CAG member
Dr Katie Harron	CAG member
Mr Tony Kane	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from University College London Hospital NHS Foundation Trust (UCLH) set out the purpose of medical research, of administering patient surveys to help determine if there are clinically significant differences in outcomes in 2021 for teenagers and young adults (TYA) with cancer receiving 'joint care' compared to all or no care in a teenagers and young adults Principal Treatment Centre (TYA-PTC).

In England, approximately 2,100 new cancers occur in TYA aged 16-24 annually. Cancer is the most common cause of non-accidental death in TYA with around 300 young people each year dying from their cancer. Five-year survival for young people with cancer varies from 50-98%, with improvements in the last 20 years lagging those observed for adults. TYA treatment-related morbidity is considerable, as are interruptions to social development, education, and employment, highlighting the importance of considering non-clinical outcomes, such as quality of life (QoL), alongside clinical outcomes, such as survival, in young people with cancer.

Specialist services provide care in thirteen TYA-PTCs. BRIGHTLIGHT (CAG reference: ECC 8-05(d)/2011) was a national evaluation of these TYA cancer services between 2013-2014, which included a cohort study examining differences in QoL, survival and costs of specialist care based on exposure to the TYA-PTC (all, some, or none). Results suggested young people whose care is divided between PTCs and other hospitals (joint

care) have lower quality of life than those having all their care in a PTC or no care in a PTC. New NHS commissioning guidance recommends 'joint care'. It is therefore important to assess whether the findings of BRIGHTLIGHT still hold in 2021, or whether 'joint care' can now be as good as all-TYA-PTC and no-TYA-PTC care. This application, BRIGHTLIGHT-2021 will provide the evidence to inform TYA cancer care policy, which will in turn maximise better outcomes for young people with cancer.

The eligible cohort is all people aged 16-24, 4-6 months after a cancer diagnosis, screened by the direct care team over a 10 month time period, which the applicants estimate to number approximately 1000 people. Support is required in this application to allow members of the direct care team at the 13 TYA-PTCs to disclose a password protected Excel file containing patient forename, surname, date of birth, NHS number, gender, address, and details of any potential challenges to participation, i.e., non-English speaking, visual impairment to Quality Health. The methodology is the same as that used for the National Cancer Patient Experience Survey (CAG reference 21/CAG/0084) and also similar to the methodology trialled in BRIGHTLIGHT (CAG reference: ECC 8-05(d)/2011). Quality health will then send a postal invitation letter including a patient information sheet to the cohort, containing a survey about QoL, other factors including social support, and their experience of their cancer journey and care. Two reminders will be sent to non-responders. Before each correspondence is sent, Quality Health will run a deceased check. Survey responses will be taken as implied consent to take part in the survey. However, further linkage will be undertaken with 's251' support as the legal basis.

Survey responses, in addition to NHS Number, postcode and date of birth, (but not name and address) will be disclosed from Quality Health to NHS Digital. The survey responses will then be linked to clinical data from National Cancer Registration and Analysis Service (NCRAS) including cancer (type, staging), treatment (systemic anti-cancer therapy, radiotherapy, surgery), survival at 1 year after diagnosis, and hospital inpatient and outpatient activity in the first six months after diagnosis. Identifiable data will be modified from full dates to current age, age at diagnosis, survival time (based on date of death derived from the registry data) and postcode will be modified to Lower Layer Super Output Area (LLSOA) and Index of Multiple Deprivation (IMD) score. All items of confidential patient information will then be deleted prior to analysis. Analysis will be undertaken by a member of the UCLH research team who will be seconded to NCRAS. Anonymous data will be disclosed to UCLH for further analysis, and this does not require CAG support.

A recommendation for class 1, 2, 3, 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	All (Approximately 1000) young people in England aged 16-24 years, between 4-6 months of a new cancer diagnosis. Screening will take place over a 10 month time period, which will start once all approvals are in place.
Data sources	4. 13 TYA treatment centre MDTs 5. National Cancer Registration and Analysis Service (NCRAS) – (Hospital Episode Statistics – (HES) data is already incorporated into NCRAS dataset as standard). Controlled currently by PHE, but this is being transferred to NHS Digital, and NCRAS is currently held at NHS Digital.
Identifiers required to send out questionnaire (including DBS check)	13. Name 14. Date of birth, 15. NHS number, 16. gender, 17. Full address including postcode
Identifiers required for linkage purposes	1. NHS Number 2. Postcode 3. Date of birth
Identifiers required for analysis purposes	18. Gender 19. Ethnicity 20. Postcode modified to LLSOA and IMD Can be considered anonymous to those undertaking analysis.

Additional information	young people's details will be uploaded to Quality Health on a monthly basis. A pseudonym is applied by Quality Health on receipt. Linkages with HES and NCRAS will be undertaken at 1 year post an individuals inclusion.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Please provide a Favourable Opinion from the REC (as noted in standard conditions of support below).**

This was provided to the CAG inbox on 18th August 2021.

2. **Please provide an updated poster, which clearly explains the linkage involved, and alter the statement "*Quality Health... will only use your details to carry out the survey"*.**

The applicant provided an updated poster and the CAG were content with this response.

3. **Please provide an updated survey cover letter and reminder letters ensuring they refer to the linkage, and contain details as to who to contact to register objections, including an email address for opting out of repeated contacts and or linkage.**

The applicant provided an updated cover letter and reminder letters which covered the points raised by the sub-committee, and the Members were content with this response.

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. Favourable opinion from a Research Ethics Committee. **Confirmed 18 August 2021.**

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

   Due to the number of organisations involved it is the responsibility of University College London Hospitals NHS Foundation Trust as controller, to ensure that all organisations processing confidential patient information without consent 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 a practice. This will not be individually checked by the Confidentiality Advice Team (CAT), as there are more than 5 organisations involved.

e. 21/CAG/0137 - IBIS-II-O: Long term observational follow up of previous participants of the IBIS-II studies: DCIS and Prevention

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from Queen Mary University of London set out the purpose of medical research which aims to undertake the long-term observational follow-up of patients who were previously enrolled on a fully consented basis to the IBIS-II Prevention and DCIS clinical trials.

The IBIS studies have investigated preventative agents for breast cancer since 1992. IBIS-II Prevention compared tamoxifen to placebo in women with increased risk of breast cancer. IBIS-II DCIS compared anastrozole to tamoxifen in women with excised ductal carcinoma in situ (DCIS). Active treatment in the trials stopped in 2017; however, follow-up continues to determine the benefit and risk involved in preventative treatments. The current scope of the follow-up, which was described in the initial study protocols, proceeds with support under the Regulations as it was determined that the consent taken from women did not sufficiently describe the follow-up which would be carried out. In this application, the applicants are seeking support to carry out further longer-term follow-up of the patient cohorts beyond the scope of the initial protocols, which were planned to come to an end in 2022. The follow-up process will require data collected from registries only, as this provides sufficient and accurate information to enable annual patient questionnaires to be terminated.

The follow-up within this protocol will involve flagging the patient cohorts within cited NHS administrative datasets to enable longer-term follow-up to be undertaken in line with the scientific objectives set-out within the initial clinical trials. Further follow-up data may also be requested from the patient's GP where necessary. The purpose of the follow-up is to enable longer monitoring of the longer-term safety profile of the preventative treatments and gain an understanding of potentially related events, including other cancers, bone fractures and cardiovascular events.

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

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	Patients who were previously enrolled on the IBIS-II Prevention trial (3864 women) and IBIS-II DCIS trial (2980 women). This covers 2,867 patients in England and Wales.
Data sources	1. Existing IBIS-II trial databases held at Queen Mary of London University

	2. NHS Digital; a. Hospital Episodes Statistics (HES) b. National Cancer registry data, (NCRAS) (originally planned to acquire from Public Health England (PHE) also, however it is understood that this dataset will be transferred to NHS Digital). c. ONS Mortality data 3. Digital Health & Care Wales (DHCW) (Formerly known as NHS Wales Informatics Service, (NWIS) a. Patient Episode Database for Wales (PEDW) 4. National Cancer Registration and Analysis Service, Public Health Wales 5. GP surgeries
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode 5. Study ID
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Gender
Additional information	Extracts will be undertaken annually

Confidentiality Advice Team advice

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

Public interest

The CAT 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 applicants were seeking to improve knowledge of the long-term outcomes of women treated for breast cancer. Breast cancer is the most commonly diagnosed cancer within women in the UK. The CAG previously noted that any deviation in the outcomes of the patient groups involved may not be seen for a number of years post-treatment and accepted the rationale for carrying out longer-term follow-up. The Group previously accepted that collecting information about the treatment of breast cancer was in the public interest.

History

This letter should be read in conjunction with letters related to 19/CAG/0126 dated 23 July 2019, 20 September 2019 and 07 February 2020. This letter should also be read in conjunction with letters related to 20/CAG/0134 and 20/CAG/0135 dated 20 November 2020.

The CAT considered the long history of this application. The study was initially supported in 2012 as a clinical trial of an investigational medicinal product (CTIMP) to allow long term follow up with two administrative data sets (ECC 6-02 FT8/2012 and ECC 6-02 FT9/2012). In September 2019, a submission (19/CAG/0126) was supported following CAG advice to continue the long term follow up as an observational study (rather than a CTIMP) and continue linkage with a number of datasets, which combined and superseded the two 2012 applications. Following this, ECC 6-02 FT8/2012 and ECC 6-02 FT9/2012 were expired. However, in January 2020 the CAG were informed that the MHRA rejected this change due to being unable to transfer the IBIS-II CTIMP studies (Prevention and DCIS) UK cohort to 19/CAG/0126 due to the main CTIMP study remaining open for data collection in other countries. As such, 19/CAG/0126 was expired and, exceptionally, the two applications from 2012 were reinstated through an amendment. This was on condition that two revised applications were submitted within three months, to ensure clarity. These were 20/CAG/0134 and 20/CAG/0135.

The applicant informed the CAG that the main CTIMP studies are now closing, and wished to re-activate 19/CAG/0126. This was discussed with the Chair who requested a refreshed application to reflect and update 19/CAG/0126 and to replace 20/CAG/0134 and 20/CAG/0135. This application, 21/CAG/0137, is this revised application.

Whilst the CAT noted this history, it was felt that the underlying purpose of why support has been in place did not change significantly with this application, and it is for administrative clarification only.

Scope of support

The applicants were seeking support to follow-up patients until June 2026 and also to change how the follow-up information was collected. The applicants had been sending annual questionnaires to participants to collect follow-up information. Follow-up data was also obtained from NHS administrative datasets held by specified sources. Over time, the applicants had found that the information received from the administrative datasets was more complete than that received from patients. These linkages also meant that information could be obtained for patients lost to follow-up. The CAG previously noted that the protocol for 19/CAG/0126, which would replace the two previous studies, was less intrusive for patients and place less burden on the clinical teams.

The applicants also sought support to contact the GPs of patients to request further data if the information from the administrative datasets was incomplete. The Group asked as part of a review of 19/CAG/0126, how often the applicants anticipated that they would need to contact the patients' GPs for further information. As part of the response to provisional outcome, the applicant clarified that patients' GPs would only be contacted for further details if full information on the primary end point, breast cancer, had not been received. This information may include pathology information or confirmation of the date the diagnosis of breast cancer was made, as these items were needed to contribute information to the applicants primary and secondary objectives. The applicants anticipated that would not be a regular occurrence, as most of the required information should be provided from national cancer registry data. They could not give a definitive answer on how often this would need to be done but estimated that it may be required for 10% of cases. The Sub-Committee noted this and raised no further queries.

Data would be collected on patients in Scotland and Northern Ireland. Members previously noted that some patients may have moved between England and Wales and these countries and asked as part of a review of 19/CAG/0126 whether support was being sought for cross-border follow-up. As part of the response to provisional outcome, the applicant advised that they received detailed information from NHS Digital and other registries on different event types. These event types included whether a patient was registered in a different devolved nation. NHS Digital sent specific codes for all events, which involved codes for cancer diagnoses and deaths, and codes for which devolved nation the patient was registered in. Similar codes were received from the National Services in Scotland and Northern Ireland, and the applicants were able to track patients who moved from Scotland to England and vice versa. The Sub-Committee noted this information and raised no further queries.

Practicable alternatives

The CAT 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 Group previously considered whether consent was possible, as the applicants would be writing to all patients to inform them of this follow-on. Members noted that the returns from this type of contact were often low. The applicants had explained that a large proportion of patients may be deceased or no longer under routine hospital follow-up. Seeking consent for this follow-up application would place an unnecessary burden on both patients and clinical sites, as well as the central trial co-ordination team.

Patients had previously consented to participate in the IBIS clinical trials. This follow-on required no further interventions and patients had been made aware that they would be followed-up after participating in the clinical trials.

NHS Digital had previously informed the applicants that the consent in place for the two previous applications was not valid for the linkage with wider datasets it retained. The applicants had submitted this new application in order to obtain support to carry out the extended follow-up without seeking further consent from patients.

The Group considered whether the proposed activities would be considered as in keeping with the scope of activities which had been consented to by participants within the historic trials. Members determined that the study activities this was the case; however, it was recognised that the consent was not previously considered valid for the necessary linkage. The Group noted that it was sensible for the applicants to re-apply for support under the Regulations to legitimise the long-term future of this project. The Group previously accepted the rationale given for not seeking consent from patients.

• Use of anonymised/pseudonymised data

Confidential patient information is required to facilitate linkage with wider administrative datasets which could not be otherwise achieved.

<u>'Patient Notification' and mechanism for managing dissent</u>

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 <u>inform</u> 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 explained that they had maintained contact with participants in the clinical trial through the provision of patient updates and newsletters. The applicants intended to send all participants a direct notification about this extended follow-up, which will continue until 2026. The patient notification letter contained information on how to withdraw from the ongoing follow-up. A telephone number, e-mail address and link to the online withdrawal form were provided. Any opt-out would be acted upon within 10 working days of receipt and confirmation provided to the patient.

The applicants also intended maintain ongoing contact with patients and to write to participants to inform them of any significant events or publications which have been made from the study findings. The notification letter had been provided for review, alongside a recent newsletter. Wider information about the IBIS studies and the follow-up were available on the IBIS website. Members were previously assured by the communications strategy set-out to support this application and raised no queries.

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 Queen Mary University of London Patient and Public Involvement Group was approached about the study in 2018. The group is comprised of members of the public who were interested in cancer, are the relatives or carers of those with cancer, or have personal experience of cancer. The group meets in person once a year and consults on different research proposals via email. Members discuss, advise, and provide feedback on clinical trial information provided to the public or to cancer patients to improve the quality, experience and relevance of clinical research.

The group reviewed the study protocol and a copy of the patient notification letter. The issue of approaching the cohort for consent was also discussed. The group commented that they felt it was proportionate to not seek further consent, and that participants would not overall have any concerns being transferred to a new protocol as they are a committed cohort and unlikely to object. The group reviewed the information materials and the changes it recommended had been implemented by the applicant.

The CAG previously noted as part of a review of 19/CAG/0126 that it was unclear how many patients from the patient and public involvement group had been involved in the discussion about this new application. Members requested that more details about the questions asked were provided, and that the number of patients involved in the discussion was clarified. As part of a response to provisional outcome, the applicant explained that that the Queen Mary Trials Advisory Group (QMTAG) was comprised of nine volunteers. Their role was to review study documents, such as the patient information sheets, consent forms, research proposals, as well as existing studies undergoing ethical review. The group meet face-to-face annually, and researchers

within the Cancer Prevention Trials Unit (CPTU) can arrange talks with the QMTAG volunteers and discuss the ongoing studies and their status. Most volunteers are female, with a variety of socioeconomic backgrounds. Members were aged between 30 and 70 years of age, approximately. Members were patients who had been treated for endometrial, breast or bowel cancer, and rheumatoid arthritis, depression, diabetes, or autoimmune disease. Nine volunteers had been contacted via e-mail to give feedback on this application. The e-mail questions sent to the volunteers and the volunteers' responses were provided with the applicants response to the CAG Provisional Outcome. The Sub-Committee noted the information provided and raised no further queries.

The applicants have again consulted their Patient and Public Involvement Group in 2020 regarding the intention to conduct follow up via centrally held NHS registries, and have strong support to continue collecting long term follow up data without further consent. The CAT felt that to accept the patient and public involvement undertaken as sufficient would be in keeping with the previous decisions of CAG.

Exit strategy

No end-point for support had been included in the original applications. As part of 19/CAG/0126 the applicants were seeking support to follow-up patients until 2026. The Group previously noted that 2047 was mentioned as a wider point in the application and queried whether this related to data retention. Clarification was sought from the applicant around these points, and as part of the response to provisional outcome the applicant responded that the Archiving Policy for the Joint Research Management Office at Queen Mary University of London required that all documentation was archived for 20 years following study completion. This policy also complied with the policies on Retention and Disposal of Records at Bart's Health Trust and Queen Mary University of London, as well as the Data Protection Act 2018. The data would be stored until 2047, after which all study documents will be destroyed. The Sub-Committee noted this information and raised no further queries.

The end point for patient follow up for 21/CAG/0137 is June 2026, and the end point for 's251' support will be the time point that any confidential patient information collected without patient consent is deleted.

Confidentiality Advice Team conclusion

It was noted that no changes to people, purposes, data and flows were flagged to the CAT by the applicant. The CAT 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. This application supersedes 20/CAG/0134 and 20/CAG/0135, which in turn superseded 19/CAG/0126.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 06 July 2021**

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

   The NHS Digital **20/21** DSPT review for **Barts CR-UK Cancer centre** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 25 August 2021).

   Regarding other data processors including GP practices, due to the number of organisations involved it is the responsibility of Queen Mary University of London as controller, to ensure that all organisations processing confidential patient information without consent meet the minimum required standard in complying with DSPTs, or CPiPs in Wales, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a practice. As there are 5+ organisations these will not be individually checked by the Confidentiality Advice Team (CAT).

2. New Amendments

18/CAG/0054 – Lung cancer screening study using low dose CT to support the development of blood tests for early cancer detection

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study investigates the feasibility of introducing low dose computed tomography (LDCT) screening to a group of adults at high risk of lung cancer. The study has support to allow the research team access to GP record systems in order to identify and invite potential participants to the study. The study also has support to analyse the data of both those who attend and those who do not.

This amendment sought support for GRAIL Bio UK Ltd to access the trial database for the purpose of system maintenance, which may lead to confidential patient information becoming visible as fixes are processed. The contractors were previously appointed via honorary contracts with UCL, however, this meant CAG support was requested for each engineer to work on the database. This process was administratively burdensome and therefore this amendment seeks support for GRAIL Bio UK Ltd to be a data processor in their own right, in order to undertake software maintenance and updates without seeking a UCL honorary contract for each new engineer.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT), as a previous amendment request for maintenance of the trial database was considered by a Sub-Committee and supported on 14 October 2019. A second amendment considering the same issue was supported on 17 August 2020, and a third on 10 March 2021. This amendment is for permanence of these previous amendments. The CAT recognised that the maintenance of the trial database was an essential element to ensuring the supported project can successfully proceed.

It was noted that the Confidentiality Advisory Group (CAG) had already determined that the project had a medical research purpose which was strongly in the public interest. The CAT recognised that the Sub-Committee had previously determined that database maintenance was not listed as a medical purpose in its own right within section 251(12)

of the NHS Act 2006, however, the Group was assured that the necessary processing for this task was essential to achieving the overarching medical research purpose of the study.

The CAT understood the rationale provided and were content to provide a recommendation of support to the project.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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: **Confirmed:**

   The NHS Digital **19/20** DSPT reviews for **University College London Hospitals NHS Foundation Trust, University College London - School of Life and Medical Sciences, CFH Docmail Ltd and Amazon Web Services** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 30 July 2021)

   The NHS Digital **20/21** DSPT review for **GRAIL Bio UK Ltd** was confirmed as **'Standards Met'** on the NHS Digital DSPT Tracker (checked 30 July 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed within the scope of existing ethical opinion**

19/CAG/0131 – Systems research into child-centred medical education v1.0

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study has support for incidental access to confidential patient information during the course of observations of medical trainees undertaken at staff multidisciplinary team meetings and handovers onsite at University Hospitals Southampton NHS Foundation Trust.

This amendment sought support to extend the study duration until 30 March 2022, due to COVID-19 pandemic. There are no changes to the research design.

Confidentiality Advisory Group advice
The amendment requested was considered by the Confidentiality Advice Team. No queries were raised regarding this amendment.

Confidentiality Advisory Group advice conclusion
In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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: **Confirmed:**

   The NHS Digital 19/20 DSPT review for **University Hospitals Southampton NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 30 July 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **REC confirmed non substantial by email 30 June 2021**

16/CAG/0058 – National Maternity and Perinatal Audit (NMPA)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from English & Welsh NHS Trusts to the Royal College of Obstetricians and Gynaecologists, in order to link this data with data contained in other national databases for the purpose of conducting a national, prospective, clinical audit of maternity services in England and Wales, in order to improve the quality of services and the outcomes achieved for mothers and new-borns.

This amendment sought support to extend the duration of 's251' support until 31 December 2022. This is because the National Maternity and Perinatal Audit (NMPA) contract was originally due to end on 30 June 2021, but has now been extended until 31 December 2022.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries with this amendment.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. 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:

Confirmed: The NHS Digital **20/21** DSPT review for **The Royal College of Obstetricians and Gynaecologists** was confirmed as 'Standards Met' (by email to the CAG inbox on 02 August 2021)

19/CAG/0077 – Enhanced surveillance of neonatal herpes simplex disease in UK and Irish infants less than 90 days of age.

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application uses the BPSU methodology to determine whether infants who receive prompt treatment for Herpes simplex virus (HSV) have a better outcome that those whose treatment is delayed.

This amendment sought support to extend the duration of the surveillance period by 6 months. The applicants currently have support to collect cases over a 2 year period until July 2021. This is because the study data to date appears to show that cases of neonatal herpes have declined during 2020 and 2021 compared with 2019. It is possible that transmission has declined because of reduced social interactions during the COVID 19 pandemic and therefore the applicants wish to continue the study for 6 months as COVID restrictions are lifted to determine accurate disease prevalence and a possible link with social distancing measures, as this may help in future guidance on how to avoid such infections.

This amendment also sought support to send an additional short follow-up questionnaire at 24 months post illness, in addition to the 12 month questionnaire already sent. This is in order to identify episodes of neonatal herpes recurrence between 12 and 24 months of age, once the children are off Acyclovir prophylaxis, which tends to be given to prevent recurrence until around 12 months of age.

These changes would extend the study duration until January 2024.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT understood that these changes are as a result of the pandemic, and there are no alterations from the standard BPSU methodology.

Confidentiality Advisory Group advice conclusion
In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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: **Confirmed:** The NHS Digital **19/20** DSPT review for **Brighton And Sussex University Hospitals NHS Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 02 August 2021).

   Applicant has confirmed that **Brighton And Sussex University Hospitals NHS Trust** has recently merged with **Western Sussex Hospitals NHS Trust (RYR)** to create **University Hospitals Sussex NHS Foundation Trust**, ODS code listed as RYR. As the DSPTs appear to still be under the original Trust names, this amendment has been supported on the basis of the above Trust being compliant.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non-substantial 30 July 2021**

19/CAG/0220 – Linked de-identified research database for congenital anomaly outcomes

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study has support to allow the disclosure of confidential patient information from localised regional registers and Public Health England to St George's University of London and subsequent disclosures to NHS Digital, NHS Wales Informatics Service.

This amendment sought support to extend the duration support required until November 2021, as the applicant has experienced a number of delays outside of their control, including the pandemic.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. No queries were raised regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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: **Confirmed:**

   The NHS Digital **19/20** DSPT review for **NHS Digital, St George's Medical School, and Public Health England, and the equivalent for Department for Education** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 30 July 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Original REC opinion provides support until 16 November 2021**

16/CAG/0064– The UK Renal Registry: A Research Database

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Dr Tony Calland MBE	CAG Chair

Context

Amendment request

The applicant has requested various amendments listed as 1-5 in the CAG amendment form. Changes 1-4 have no impact on CAG support. Changes 1-3 are regarding additional clinical data from PHE regarding vaccine data, NCARDS data, and peritoneal culture data, which does not include any new identifiable data items or flows. Change 4 is regarding sending pseudonymised data to European Renal Association–European Dialysis and Transplant Association (ERA-EDTA). Therefore the only change requested to CAG support is change 5.

This amendment therefore seeks support for the UK Renal Registry (UKRR) to transfer clinical data alongside identifiers to NHS Digital, for the purposes of linking with data from National Institute for Cardiac Outcomes Research (NICOR), in order to establish a centrally held cardiorenal audit and research database. This platform would enable audit and research of patients who have renal and/or cardiac disease. Currently, although patients frequently have both conditions, their care and outcomes are captured in separate data sources. Only by combining all data sources is it possible to capture the extent of cardiac complications and care in renal patients, and vice versa. Data would not leave this secure platform, approved researchers would be enabled by NHS Digital to log into the platform to carry out analyses, with researchers keeping log-files and aggregate analytic results.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair was content that amendments 1-4 did not constitute any changes to support provided under Regulation 5. Amendment 5 is to create a new linkage between the UKRR,

NICOR and NHS Digital, so that the full benefit of data collected both for renal disease and cardiac disease can be incorporated into a single place. This dataset will allow researchers to use the dataset within the confines of NHS Digital so no new data is disseminated to researchers outside of NHS Digital. The Chair noted that this has a medical purpose and strong public interest and was content to recommend support.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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 **(Confirmed – The Renal Association has a confirmed 'Standards Met' grade on DSPT submission 2019/20 by check of the NHS Digital DSPT tracker on 29 July 2021).**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 03 August 2021**

16/CAG/0153– UK Renal Registry

Name	**Capacity**
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Dr Tony Calland MBE	CAG Chair

Context

Amendment request

The applicant has requested various amendments listed as 1-5 in the CAG amendment form. Changes 1-4 have no impact on CAG support. Changes 1-3 are regarding additional clinical data from PHE regarding vaccine data, NCARDS data, and peritoneal culture data, which does not include any new identifiable data items or flows. Change 4 is regarding sending pseudonymised data to European Renal Association–European Dialysis and Transplant Association (ERA-EDTA). Therefore the only change requested to CAG support is change 5.

This amendment therefore seeks support for the UK Renal Registry (UKRR) to transfer clinical data alongside identifiers to NHS Digital, for the purposes of linking with data from National Institute for Cardiac Outcomes Research (NICOR), in order to establish a centrally held cardiorenal audit and research database. This platform would enable audit and research of patients who have renal and/or cardiac disease. Currently, although patients frequently have both conditions, their care and outcomes are captured in separate data sources. Only by combining all data sources is it possible to capture the extent of cardiac complications and care in renal patients, and vice versa. Data would not leave this secure platform, approved researchers would be enabled by NHS Digital to log into the platform to carry out analyses, with researchers keeping log-files and aggregate analytic results.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair was content that amendments 1-4 did not constitute any changes to support provided under Regulation 5. Amendment 5 is to create a new linkage between the UKRR, NICOR and NHS Digital, so that the full benefit of data collected both for renal disease and cardiac disease can be incorporated into a single place. This dataset will allow researchers to use the dataset within the confines of NHS Digital so no new data is disseminated to researchers outside of NHS Digital. The Chair noted that this has a medical purpose and strong public interest and was content to recommend support.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and

therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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 **(Confirmed – The Renal Association has a confirmed 'Standards Met' grade on DSPT submission 2019/20 by check of the NHS Digital DSPT tracker on 29 July 2021).**

19CAG/0166 – HPS2-THRIVE trial legacy study: long-term follow-up of participants using electronic health records

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Dr Tony Calland MBE	CAG Chair

Context

Amendment request

This study from the University of Oxford set out the purpose of medical research which aims to undertake long-term follow-up of patients who were previously recruited to the HPS2-THRIVE Trial. Support is in place to allow the disclosure of trial IDs from University of Oxford to NHS Digital to facilitate linkage with standard administrative datasets.

The data sources required are listed in the original outcome letter as the following:

1. Existing HPS2-THRIVE Trial data
2. HES, NHS Digital
3. Mental Health Minimum Dataset, NHS Digital
4. ONS Mortality Information, NHS Digital.

An amendment in November 2020 provided support for applicants to access Cancer Registration data provided by NHS Digital for analysis purposes (as well as the validation and linkage already covered by the original support).

The identifiers required for analysis are listed as Study ID only, and support has not previously been specifically provided for the flow of information back to the applicants from NHS Digital.

NHS Digital have requested an amendment to clarify the specific datasets required as data sources, as the titles of these datasets have changed since support was provided, and to provide support for the flow of specified confidential patient information back to the applicants from NHS Digital.

The applicant is therefore requesting support to clarify that CAG support is in place to link to the Mental Health datasets at NHS Digital, which are now called:

1. Mental Health Minimum Dataset;
2. Bridge File: Hospital Episode Statistics to Mental Health Minimum Data Set;
3. Mental Health Services Data Set;
4. Mental Health and Learning Disabilities Data Set;

And also to link to the Demographics dataset at NHS Digital. This is in addition to the support which is already in place. Support is also required for the flow of information back to the applicant from NHS Digital, as the Cancer Registration Number is included in the dataset. NHS Digital have requested that cause of death be listed as supported individually, however, CAG would not consider this to be a direct identifier. Support is provided for the entire flow, due to the inclusion of the Cancer Registration Number, and as the applicants already retain identifiable data, it would be possible for them to re-identify these individuals.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The chair was content to provide support for this amendment to clarify the data sources and data flows.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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:
   Confirmed: The NHS Digital **19/20** DSPT review for **University of Oxford - Medical Sciences Division – Nuffield Department of Primary Care Health Sciences (EE133863-MSD-NDPCHS) and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 April 2021)

   - **CPiP Confirmation from NHS Wales Informatics Service that the appropriate security assurance is in place for the NHS Wales Informatics Services via the Caldicott Principles into Practice report (Confirmed 15 June 2020)**

   - **CPiP Confirmation from NHS Wales Informatics Service that the appropriate security assurance is in place for the Welsh Cancer Intelligence and Surveillance Unit via the Caldicott Principles into Practice report (Confirmed 09 November 2020)**

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   REC confirmed by email sent 23 March 2021 that this amendment is in scope of previous Favourable Opinion

19/CAG/0167 – SEARCH trial legacy study: long-term follow-up of participants using electronic health records

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Dr Tony Calland MBE	CAG Chair

Context

Amendment request

This study from the University of Oxford set out the purpose of medical research which aims to undertake long-term follow-up of patients who were previously recruited to the SEARCH Trial. Support is in place to allow the disclosure of trial IDs from University of Oxford to NHS Digital to facilitate linkage with standard administrative datasets.

The data sources required are listed in the original outcome letter as the following;

1. Existing SEARCH Trial data
2. HES, NHS Digital,
3. Mental Health Minimum Dataset, NHS Digital
4. ONS Mortality Information, NHS Digital

An amendment in November 2020 provided support for applicants to access Cancer Registration data provided by NHS Digital for analysis purposes (as well as the validation and linkage already covered by the original support).

The identifiers required for analysis are listed as Study ID only, and support has not previously been specifically provided for the flow of information back to the applicants from NHS Digital.

NHS Digital have requested an amendment to clarify the specific datasets required as data sources, as the titles of these datasets have changed since support was provided, and to provide support for the flow of specified confidential patient information back to the applicants from NHS Digital.

The applicant is therefore requesting support to clarify that CAG support is in place to link to the Mental Health datasets at NHS Digital, which are now called:

1. Mental Health Minimum Dataset;
2. Bridge File: Hospital Episode Statistics to Mental Health Minimum Data Set;
3. Mental Health Services Data Set;
4. Mental Health and Learning Disabilities Data Set;

And also to link to the Demographics dataset at NHS Digital. This is in addition to the support which is already in place. Support is also required for the flow of information back to the applicant from NHS Digital, as the Cancer Registration Number is included in the dataset. NHS Digital have requested that cause of death be listed as supported individually, however, CAG would not consider this to be a direct identifier. Support is provided for the entire flow, due to the inclusion of the Cancer Registration Number, and as the applicants already retain identifiable data, it would be possible for them to re-identify these individuals.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The chair was content to provide support for this amendment to clarify the data sources and data flows.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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:
   Confirmed: The NHS Digital **19/20** DSPT review for **University of Oxford - Medical Sciences Division – Nuffield Department of Primary Care Health Sciences (EE133863-MSD-NDPCHS) and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 April 2021)

- **CPiP Confirmation from NHS Wales Informatics Service that the appropriate security assurance is in place for the NHS Wales Informatics Services via the Caldicott Principles into Practice report (Confirmed 15 June 2020)**

- **CPiP Confirmation from NHS Wales Informatics Service that the appropriate security assurance is in place for the Welsh Cancer Intelligence and Surveillance Unit via the Caldicott Principles into Practice report (Confirmed 09 November 2020)**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **REC confirmed by email sent 23 March 2021 that this amendment is in scope of previous Favourable Opinion**

18/CAG/0153 – The POOL study: Establishing the safety of waterbirth for mothers and babies: A cohort study with nested qualitative component.

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study aims to evaluate whether the use of birthing pools during labour and water births leads to an increased risk in poor maternal and infant outcomes.

The study has 's251' support to enable data to flow from hospital maternity records at 26 sites, to National Neonatal Research Database (NNRD), and the support is on the basis that mothers can opt out of the study should they so wish. This is usually communicated at all sites by hand out leaflets, posters and cards for all women who use a birthing pool.

Sites who continued with waterbirths during the pandemic were also expected to continue to provide opt-out information to women. However, due to redeployment of the research midwife at Newcastle upon Tyne, all study posters were removed from the clinical areas in March 2020, which removed women's ability to opt-out. The study team have recently been made aware of this and normal practice has resumed in March 2021.

Study data relating to women who used a birth pool between 1st March 2020 and 28th February 2021 has already been captured by the electronic maternity system at the

site. Therefore, this amendment sought support to send an opt-out notification to all the mothers who used a pool at this particular site during this period. To ensure contact is appropriate, the NHS site will check all records against the NHS Spine to ensure that no contact is made with any mother / family of a deceased neonate or mother. The NHS site will post the attached document to all mothers, giving them a month to opt-out, the NHS site will then record the opt-out in the local maternity information system so the records are not used. Therefore, there is no breach in confidentiality regarding the sending of these opt-out notifications, as this will be undertaken by the direct care team, so support is not required for this element.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. This amendment will not involve further disclosure of confidential patient information, and is a way to ensure every person has the opportunity to opt-out, as per the 's251' support initially provided.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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: **Confirmed:**

   The NHS Digital **20/21** DSPT reviews for **Wellbeing Software Group Limited incorporating Healthcare Software Solutions, EuroKing, e-Healthcare Innovations (8HF02)** and **Chelsea and Westminster NHS Foundation Trust**

   were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 09 August 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 13 July 2021**

19/CAG/0027 – A diagnostic evaluation of malaria detection in patients presenting to the emergency department - a large teaching hospital retrospective cohort study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of specified confidential patient information from Manchester University NHS Foundation Trust to Public Health England in order to facilitate linkage with the National Malaria Registry.

In this amendment, the applicants are seeking to extend the duration of support to June 2022. The applicants require further time to meet the aims of their objectives, as they have experienced delays due to the Covid-19 pandemic.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT agreed that the extension was in the public interest.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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: **Confirmed:** The NHS Digital **20/21** DSPT review for **Manchester University NHS Foundation Trust** is confirmed as 'standards met' on the NHS Digital DSPT tracker (checked 29 July 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non-substantial 15 January 2021**

21/CAG/0007 – National Neonatal Audit Programme (NNAP) data flow

Name	**Capacity**
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Tony Calland MBE	CAG Chair

Context

Amendment request

The National Neonatal Audit Programme (NNAP) delivered by the Royal College of Paediatrics and Child Health (RCPCH) aims to assess whether babies admitted to neonatal units in England and Wales receive consistent high-quality care and to identify areas for service and quality improvement in relation to the delivery and outcomes of neonatal care. Support is in place to allow the disclosure of confidential patient information contained in the BadgerNet system, for Clevermed Ltd to extract confidential patient information and for further disclosure to the RCPCH Azure hosting infrastructure. RCPCH is commissioned to undertake these activities by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP).

This amendment sought support to clarify that BadgerNet ID is also being collected for the purposes of this audit, and will be held and processed by the RCPCH in addition to the key identifiers listed in the original application.

This amendment also sought support for a new flow of data from RCPCH back to the individual Trusts. This flow will contain mainly non-identifiable information, with the only identifiable data item being the BadgerNet ID. These patient episode lists are for the purposes of data quality and completeness checks, and will relate to patients cared for by that Trust only. The applicants reason that this amendment will improve the quality and completeness of the data reported by the NNAP by enabling NHS Trusts to act on any inaccuracies before the final analysis is conducted. It also will provide NHS Trusts to implement quality improvement in a more timely manner.

Confidentiality Advisory Group advice
The amendment requested was considered by Chair's Action. The Chair was content to recommend support for this amendment, and commented that support was required for the flow back to Trusts, as BadgerNet ID could be considered a direct identifier.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. 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: **Confirmed: Royal College of Paediatrics and Child Health and CleverMed Ltd have a confirmed 'Standards Met' grade on DSPT 2019/20 (by check of the NHS Digital DSPT tracker on 06 August 2021)**

19/CAG/0047 – Development and validation of a risk assessment tool for self-harm in prisoners.

Name	Capacity

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study has support to allow access to prisoner health records by a research assistant to extract wider clinical information necessary for analysis. Initially support was provided for the researcher to be present in-person in the prisons, however, due to covid-19 restrictions the researchers have requested an amendment to clarify the additional processes required in order for them to access the data required.

This amendment sought support for the additional data flow required in order for researchers to access prisoner health records. This could happen in a number of ways in addition to in-person. To access ACCT records, a link person will be identified at each prison service, who is a prison employee. This link person will disclose ACCT records to either HMP Manchester or HMP Styal (whichever is most covid secure), to the link person there. The researcher will then extract the necessary data and record on a university of Manchester encrypted laptop and in line with the original methodology. Support is therefore only needed for the disclosure of confidential patient information from participating Prisons, to HMP Manchester or HMP Styal, as the rest of the process already has support as part of the original application. Records will then be disclosed back to the participating prisons.

This amendment also sought support for Researchers based at Tees, Esk and Wear Valleys (TEWV) NHS Foundation Trust to extract data from electronic prison healthcare notes (SystmOne). Remote access to SystmOne will be facilitated by an identified host healthcare provider and will be accessed via a VPN. This support provided is not more disclosive than the original support provided, but merely provides the researcher to access remote data.

This amendment also sought support for the researcher to access *Prison* National Offender Management Information System (NOMIS) data centrally whilst based at HMP Manchester or HMP Styal. This information will be recorded on the same database as the data extracted from the ACCT documents and securely stored on the researcher's University of Manchester encrypted laptop. This support provided is not more disclosive than the original support provided, but merely provides the researcher to access remote data.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT). The purposes of this amendment do not deviate from the original support provided, and are required due to disruptions in usual ways of working during the pandemic.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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:
   Confirmed: The NHS Digital **19/20** DSPT reviews for **Greater Manchester West Mental Health NHS Foundation Trust, Maidstone and Tunbridge Wells NHS Trust, Tees, Esk and Wear Valleys NHS Foundation Trust, Spectrum Community Health CIC** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 04 August 2021)

   And the NHS Digital **20/21** DSPT review for **The Phoenix Partnership (Leeds) Ltd** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 04 August 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 20 July 2021

18/CAG/0187 – Project to Enhance ALSPAC through Record Linkage (PEARL): Phenotypic enrichment of the ALSPAC original parent/carer (G0) cohort through linkage to primary care electronic patient records and other databases.

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Tony Calland MBE	CAG Chair

Context

Amendment request

This application from ALSPAC at the University of Bristol aims to follow-up the parents and carer cohort (referenced as Generation 0 or G0) of the ALSPAC study via NHS administrative datasets held by NHS Digital, together with records held at local Trusts and primary care data from GP practices.

This amendment sought support for the addition of COVID-19 related data sourced from Public Health England (PHE). The data requested is regarding COVID-19 test records and COVID-19 hospitalisation records. The extract will include COVID-19 Hospitalisation in England Surveillance System (CHESS) records for COVID-19 admissions, care and outcomes for patients treated in Intensive Care Units in English hospitals. This data flow is already supported for the younger generation of ALSPAC participants under the CAG reference ECC 1-05(b) 2012. In order to facilitate this linkage, applicants need to disclose an encrypted file containing NHS number, Date of Birth, Postcode and Name to PHE for the G0 cohort. This is for the non-consented patients only.

This amendment sought support for the addition of COVID-19 related data sourced from NHS Digital. ALSPAC will use their existing dataflows with NHS Digital to additionally receive data from the national COVID relevant health dataset. There is no change to dataflows for this element, only to the additional data items that NHS Digital will provide to ALSPAC.

This amendment also sought support to use the flagging and tracing facilities of PHE to obtain the unique NHS-number for individual or small groups of previously unflagged ALSPAC G0 cohort participants. This is on an ad hoc basis to identify the NHS number if it is missing from ALSPAC records. In order to do this, the applicants need to disclose an encrypted file containing name, Date of Birth and postcode to PHE so they can provide the NHS number to ALSPAC. This data flow is already approved supported for the younger generation of ALSPAC participants under the CAG reference ECC 1-05(b) 2012.

Specific fair processing materials have been updated to explain this new use of COVID relevant data, alongside an updated protocol.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair was content to recommend support.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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:
   Confirmed: The NHS Digital **19/20** DSPT reviews for **North Bristol NHS Trust and Royal United Hospital Bath, and PHE** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 05 August 2021)

   The NHS Digital **20/21** DSPT reviews for **ALSPAC and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 05 August 2021)

   Pending: The NHS Digital **19/20 or 20/21** DSPT review for **UNIVERSITY HOSPITALS BRISTOL AND WESTON NHS FOUNDATION TRUST** is pending, and support is not currently in place for any data flow regarding this organisation

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 07 July 2021

18/CAG/0100 – HPS-4/TIMI 65/ORION-4: A double-blind randomized placebo-controlled trial assessing the effects of inclisiran on clinical outcomes among people with atherosclerotic cardiovascular disease

Name	Capacity
Dr Patrick Coyle	CAG vice-chair

Dr Tony Calland MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to process confidential patient information supplied by acute hospitals trusts and NHS Digital to the Clinical Trial Service Unit at the University of Oxford in order to contact patients to seek consent to include their data on a pre-screening database.

The applicants initially intended to contact patients by letter once. As part of an amendment to CAG supported on 28 September 2020, the applicants have support to send a second invitation letter to patients who did not respond to the first contact.

This amendment sought support to clarify the wording on the patient notification materials of the second invitation letter. The wording presented has been confirmed by IGARD.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair team. The Chair team requested a few minor corrections before supporting. The chairs requested more explicit wording surrounding how patients were identified, for example; 'following an automated electronic search of your electronic coded medical record held by NHS Digital'. The Chair team also requested a revision to describe CAG's role as recommending to the HRA as the decision-maker, for example '*With approval from the Research Ethics Committee and the Confientiality Advisory Group (an independent body which provides expert advice on the use of confidential patient information)'* should be altered to state something like the following; '*With Favourable Opinion from the Research Ethics Committee and support from the Health Research Authority (HRA) following advice from the Confidentiality Advisory Group (an independent body which provides expert advice on the use of confidential patient information)'*. The Chairs also requested the applicant correct the spelling of 'Confidentiality'. The chairs commented the changes should also be made to the initial invitation letter, unless it was confirmed that there is no possibility of this now being sent to anyone. This was communicated by email to the applicant on 2 August 2021.

The applicant provided updated invitation letters in response, and the Chair team advised that the responses could be viewed by the Confidentiality Advice Team (CAT). The CAT confirmed the applicant had responded to all points raised.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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. **(Confirmed – University of Oxford – Medical Sciences Division – Nuffield Department of Population Health – Clinical Trial Service Unit, and Paragon Customer Communications Ltd have confirmed 'Standards Met' grade on DSPT 2019/20 by NHS Digital DSPT Tracker checked 05 August 2021)**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 20 July 2021.**

19/CAG/0139 – The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial with economic and acceptability evaluations (GBS3)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the University of Nottingham aims to evaluate two testing approaches to identify Group B Streptococcus in pregnant women.

The applicants have existing support to process data from; electronic health records from participating maternity units in England and Wales, the National Neonatal

Research Database, Patient Episodes Dataset Wales held by the NHS Wales Informatics Service, Group Strep B Infant Sepsis reports held by Public Health England, Group Strep B Infant Sepsis reports held by Health Protection Wales, and the English Maternity Services Dataset and HES data held by NHS Digital, the Paediatric Intensive Care Audit Network (PICANet) and Badgernet (Maternity and Neonatal). Data from these sources will be processed in order to create a dataset for analysis.

This amendment sought support to include two additional NHS Trusts as new data processors - Northumbria Healthcare Foundation Trust and Frimley Health NHS Foundation Trust.

Confidentiality Advisory Group advice

The amendment requested was considered by Confidentiality Advice Team. No queries were raised regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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:
   Confirmed: The NHS Digital 19/20 DSPT review for **the University of Nottingham and the DSPT equivalent for NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 06 August 2021)

   Due to the number of organisations involved it is the responsibility of University of Nottingham, as controller, to ensure that all organisations processing confidential patient information without consent 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. These will not be individually checked by CAT as there are more than 5 organisations.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 29 July 2021

18/CAG/0063 – National Clinical Audit of Rheumatoid and Early Inflammatory Arthritis Clinical Audit

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the British Society for Rheumatology (commissioned by HQIP) set out the purpose of the National Clinical Audit of Rheumatoid and Early Inflammatory Arthritis (NEIAA). The audit aims to improve the quality of care for patients with Rheumatoid and early inflammatory arthritis (EIA) in England and Wales. The current contract period is 1 October 2017 – 30 September 2020.

This amendment sought support to extend the duration of 's251' support until September 2022, as HQIP has awarded a two year extension to the NEIAA.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT). No issues were raised regarding this amendment.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. 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:
   Confirmed: The NHS Digital **19/20** DSPT reviews for **Net Solving Ltd, and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 04 August 2021)

   Digital Health & Care Wales (DHCW) (Formerly known as NHS Wales Informatics Service, (NWIS) have provided a CPiP report (Caldicott: Principles into Practice) 19/20 and an improvement plan 20/21 dated 15th June 2020, showing a 97.5% satisfactory assessment rate).

19/CAG/0001 – National Asthma and COPD Audit Programme (NACAP): Paediatric Asthma Clinical Audit

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the Royal College of Physicians on behalf of the Healthcare Quality Improvement Partnership (HQIP), is regarding the Paediatric Asthma Clinical Audit. The audit is commissioned as part of the National Asthma and COPD Audit Programme (NACAP).

Support is currently in place to cover the collection of audit data for all admissions of children and young people to hospital with asthma attacks (ages 1-18) in England and Wales, on a continuous basis. In May 2021, the criteria were altered to remove an exclusion criteria regarding wheeze, and to amend the inclusion criteria, including ensuring certain secondary position ICD-10 codes are captured in the inclusion criteria for the Paediatric Asthma Clinical Audit in order to ensure the accurate capture of all eligible patients for the Paediatric Asthma Clinical Audit.

However the changes resulted in queries form the Trusts, seeking clarification on the inclusion criteria with a particular emphasis on entering patients with a secondary diagnosis of asthma into the audit. Therefore, this amendment sought support to further clarify the criteria, and remove '*or secondary diagnosis of an asthma attack'* from the inclusion criteria, but including this if the patient has a primary diagnosis of wheeze. The changes are also detailed below;

Include patients:

- who are between 1 and 5 years old on the date of arrival and have been admitted to a hospital paediatric service with:
    - o a primary ~~**or secondary**~~ diagnosis of an asthma attack
    - o or a primary diagnosis of wheeze **AND a secondary diagnosis** of asthma
    -
- who are between 6 and 18 years old on the date of arrival and have been admitted to a hospital paediatric service with a primary ~~**or secondary**~~ diagnosis of an asthma attack.

This amendment does not seek to change the data flows or confidential patient information collected. No additional patient identifiers beyond what has already been agreed will be collected for the Paediatric Asthma Clinical Audit.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. No queries were raised regarding this amendment, and it is noted that the applicants hope that streamlining the criteria will aid NACAP to report accurately on asthma data from children and young people.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Support under this application extends to the non-research audit purposes only. There is no support in place for the processing of information collected within the audit for research purposes.

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: **Confirmed:**

   The NHS Digital **19/20** DSPT review for **Crown Informatics** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 05 August 2021)

   The NHS Digital **20/21** DSPT reviews for **NHS Digital, and Aimes Management Services** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 05 August 2021)

   NHS Wales Informatics Service, confirmed CPIP Assurance in place

20/CAG/0143 – CTSU clinical trial follow-up service with NHS Digital to provide de-identified follow-up data for use in the EBCTCG breast cancer meta-analyses

Name	Capacity
Dr Murat Soncul	CAG alternative vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from the University of Oxford uses data collected by the CTSU clinical trial follow-up service for Early Breast Cancer Trialists' Collaborative Group (EBCTCG) to undertake meta-analyses of the comparative effects of different treatments for women with early breast cancer on death from breast cancer. Support is currently in place for 1385 patients recruited to 7 UK clinical trials into treatment of early breast cancer between 1948 and 1987.

This amendment sought support for the addition of data from 17,638 patients in 8 further clinical trials. These trials are;

- Yorkshire Conservation Trial: Entry JUL-1986 to JUN-1990; 175 entered; Principal Investigator Prof David J Dodwell
- ALMANAC Trial: Entry NOV-1999 to OCT-2003; 1031 entered; Principal Investigator Prof Robert E Mansel
- East Anglia Sentinel Node Biopsy Trial: Entry NOV-1999 to FEB-2003 (298 entered; Principal Investigator Prof A D Purushotham
- BASO II: MAR-1992 to OCT-2000; 1158 entered; Principal Investigator Prof Roger Blamey; data held by Stephen Duffy
- C.R.C. Under 50s Trial (part of 'ZIPP'): Entry OCT-1987 to MAR-1999; 208 entered; Principal Investigator Prof M Baum; data holder Allan Hackshaw
- C.R.C. Over 50s Trial: Entry JAN-1987 to FEB-1997; 3888 entered; Principal Investigator Prof M Baum; data holder Allan Hackshaw
- A.N.Z. DCIS Trial: Entry MAY-1990 to OCT-1998; 1514 entered in UK; Principal Investigator in UK Prof Jack Cuzick
- ATAC Trial: Entry JUL-1996 to MAR-2000; 9366 entered; Principal Investigator Prof M Baum; data holder Jack Cuzick

The flow of data is slightly different from the original study design. This amendment sought support for the new data flows, which are as follows; confidential patient information alongside a pseudo-identifier to be sent from the participating trials to the applicants at University of Oxford (CTSU-ctfs). Confidential patient information alongside pseudo-identifiers will then be disclosed from University of Oxford to NHS Digital, (instead of direct from individual trialists), for the purposes of linkage with Hospital Episode Statistics (HES), Demographics, Office for National Statistics (ONS) Civil Registration -Deaths and Cancer Registration datasets at NHS Digital. NHS Digital will disclose a pseudonymised dataset back to the applicant who will delete any identifiable information retained. The privacy notice will be updated.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The CAG Alternate Vice-Chair reviewed this amendment request, and considered that the applicants provided a strong public interest justification for including the additional data. The Alternate Vice-Chair was content that altering the data flow to come through CTSU-ctfs would be a helpful standard, given that the applicants are increasing the number of contributing trials. The CAG Alternate Vice-Chair commented that there did not seem to be any suggestion to add more clarity on the role of the CTSU-ctfs, which may be something applicants could consider, but this is not a condition of support.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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:
   Confirmed: The NHS Digital **20/21** DSPT review for **University of Oxford – Medical Sciences Division – Nuffield Department of Population Health and NHS digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 09 August 2021)

   Due to the number of additional organisations involved, it is the responsibility of University of Oxford, as controller, to ensure that all organisations processing confidential patient information without consent 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 a practice. As there are more than 5 organisations, DSPTs will not be individually checked by the Confidentiality Advice Team (CAT).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 13 July 2021**

CAG 8-02 (a)/2014 – Assuring Transformation: Data collection by Clinical Commissioning Groups to populate patient registers and reporting

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG vice-chair

Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

A suite of three applications had been presented by NHS England, on behalf of Clinical Commissioning Groups, to reflect the different data flows involved in the initiative known as 'Assuring Transformation'. The overarching purpose of these data flows was stated to ensure that a commissioner is always monitoring the overall management of patient care through the activity of 'case management'. Case management had been defined at time of original consideration as activities by certain roles to ensure the continuity and quality of care delivered by healthcare providers over the period of the patient's care and to ensure the appropriate support is provided.

The original intention of the application was that Assuring Transformation (AT) would be time-limited and would be stood down once the applicants had worked with NHS Digital to reconcile the Mental Health Services Data Set (MHSDS) and AT datasets. However the process has been more complex than anticipated and the aim is no longer for AT to be stood down; the aim is now for AT to be the primary data source, with data pulled from MHSDS where possible.

This amendment sought support to enable the flow of minimum confidential patient information (Name, Date of Birth, NHS Number, hospital provider and site) from providers to commissioners (who should already have this information as they are commissioning the patient's care), where patients have been identified as inpatients in-scope of Transforming Care (TC) through the MHSDS but are not being recorded in AT.

At present there are many more patients being identified through the MHSDS as in-scope of AT than there are recorded in the AT data set. At the end of April 2021 the reported number of inpatients in the MHSDS was 3,415. This compares to 2,100 in AT at the same point in time. This amendment would enable NHSE/I to identify whether there are patients who should be recorded on AT but who are not at present. If there are patients identified as missing from AT, NHSE/I and NHS Digital will follow-up with commissioners to ensure they are recorded on AT. The applicant has indicated support will be required for this amendment until September 2022.

Confidentiality Advisory Group advice

The amendment request was considered by Chairs Action. The Chairs considered that this is a very sensitive and important application, as it arose from very poor care of these patients. The Chairs felt it is very important that the applicants are able to reconcile the differences in numbers requiring transforming care. It was noted that this project is about improving direct patient care for a specific group. And the role of the commissioners is unusual, in that they are involved in individual case management. The Chairs therefore recommended support for this amendment to allow sharing of data between providers and commissioners, in order to ensure that all patients requiring transforming care are able to benefit from it.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation of suitable security arrangements via IG Toolkit submission.
    - The NHS Digital **2019/20** DSPT review for **NHS England** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 2 August 2021)

CAG 8-02 (b)/2014 – Assuring Transformation: Data collection by Clinical Commissioning Groups to populate patient registers and reporting

Name	**Capacity**
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

A suite of three applications had been presented by NHS England, on behalf of Clinical Commissioning Groups, to reflect the different data flows involved in the initiative known as 'Assuring Transformation'. The overarching purpose of these data flows was stated to ensure that a commissioner is always monitoring the overall management of patient care through the activity of 'case management'. Case management had been defined at time of original consideration as activities by certain roles to ensure the continuity and quality of care delivered by healthcare providers over the period of the patient's care and to ensure the appropriate support is provided.

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Confidentiality Advisory Group advice

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specific group. And the role of the commissioners is unusual, in that they are involved in individual case management. The Chairs therefore recommended support for this amendment to allow sharing of data between providers and commissioners, in order to ensure that all patients requiring transforming care are able to benefit from it.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation of suitable security arrangements via IG Toolkit submission.
    - The NHS Digital **2019/20** DSPT review for **NHS England** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 2 August 2021)

CAG 8-02 (c)/2014 – Assuring Transformation: Data collection by Clinical Commissioning Groups to populate patient registers and reporting

Name	**Capacity**
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

A suite of three applications had been presented by NHS England, on behalf of Clinical Commissioning Groups, to reflect the different data flows involved in the

initiative known as ‘Assuring Transformation’. The overarching purpose of these data flows was stated to ensure that a commissioner is always monitoring the overall management of patient care through the activity of ‘case management’. Case management had been defined at time of original consideration as activities by certain roles to ensure the continuity and quality of care delivered by healthcare providers over the period of the patient’s care and to ensure the appropriate support is provided.

The original intention of the application was that Assuring Transformation (AT) would be time-limited and would be stood down once the applicants had worked with NHS Digital to reconcile the Mental Health Services Data Set (MHSDS) and AT datasets. However the process has been more complex than anticipated and the aim is no longer for AT to be stood down; the aim is now for AT to be the primary data source, with data pulled from MHSDS where possible.

This amendment sought support to enable the flow of minimum confidential patient information (Name, Date of Birth, NHS Number, hospital provider and site) from providers to commissioners (who should already have this information as they are commissioning the patient’s care), where patients have been identified as inpatients in-scope of Transforming Care (TC) through the MHSDS but are not being recorded in AT.

At present there are many more patients being identified through the MHSDS as in-scope of AT than there are recorded in the AT data set. At the end of April 2021 the reported number of inpatients in the MHSDS was 3,415. This compares to 2,100 in AT at the same point in time. This amendment would enable NHSE/I to identify whether there are patients who should be recorded on AT but who are not at present. If there are patients identified as missing from AT, NHSE/I and NHS Digital will follow-up with commissioners to ensure they are recorded on AT. The applicant has indicated support will be required for this amendment until September 2022.

Confidentiality Advisory Group advice

The amendment request was considered by Chairs Action. The Chairs considered that this is a very sensitive and important application, as it arose from very poor care of these patients. The Chairs felt it is very important that the applicants are able to reconcile the differences in numbers requiring transforming care. It was noted that this project is about improving direct patient care for a specific group. And the role of the commissioners is unusual, in that they are involved in individual case management. The Chairs therefore recommended support for this amendment to allow sharing of data between providers and commissioners, in order to ensure that all patients requiring transforming care are able to benefit from it.

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation of suitable security arrangements via IG Toolkit submission.
    - The NHS Digital **2019/20** DSPT review for **NHS England** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 2 August 2021)

15/CAG/0119– MBRRACE-UK – Delivering the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP)

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG vice-chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This Healthcare Quality Improvement Partnership (HQIP) commissioned activity from University of Oxford set out the purpose of the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP) which is a national programme that aims to assess quality and stimulate improvement in safety and effectiveness in maternal, newborn and infant healthcare by systematically enabling clinicians, managers and policy makers to learn from adverse events.

Support under the Regulations was given to cover access to confidential patient information from ONS and NHS Trusts. Patients treated between 1 January 2009 and 31 March 2017 are included, and this has since been extended until 30 September 2021.

Support under the Regulations had previously been provided to the applicants to additionally retain identifiable data about all women who died as a maternal death from 1st January 2009 onwards, until 30 September 2021, whilst a trusted third party, NHS Digital, was approached for this retention. No retention arrangement had been secured with NHS Digital, and it has further been confirmed that NHS Digital are unable to retain this data. Discussions with the Office for National Statistics (ONS) are temporarily halted due to disruptions caused by the pandemic. The applicant has therefore submitted the proposed amendment to extend the scope of support so that the MBRRACE-UK collaboration could retain this data set up to 30 September 2022 in line with the current funding of the overarching MBRRACE-UK programme.

This amendment sought support to extend the duration of 's251' support in order to include patients treated between 1 January 2009 and 30 September 2022, in line with the extension of the contract with the commissioners, HQIP.

This amendment also sought support under the Regulations for MBRRACE-UK to continue to hold the identifiable data about all women who died as a maternal death from 1st January 2009 onwards until 30 September 2022. The applicants argue that it is in the public interest the retain these identifiers, in the event that it is necessary to identify specific women in the future for, for example, a retrospective review of the care that they received.

This amendment also sought support to undertake linkage of the maternal mortality data collected as part of MBRRACE-UK with Hospital Episode Statistics (HES) data by NHS Digital for the purposes of receiving data relating to the detailed breakdown of ethnicity associated with maternity hospital episodes. Applicants will provide NHS Digital with confidential patient information regarding all women who have died in England and Wales as a maternal death from 1 January 2009 until 30 September 2022 in order for NHS digital to link these women to HES data and provide back a de-identified dataset containing unit record level data of all the women who have died and all the women who have survived. This is requested in order to calculate, by more specific categories of ethnicity, ethnic-specific maternal mortality and morbidity rates, which the applicants hope will enable policy makers, clinicians and public health practitioners to focus preventive actions at the most appropriate targets which underlie the wide disparities and inequalities in outcomes. Support is also required for the flow of data back to the applicant, as the applicant will be able to re-identify the dataset.

This amendment also sought support to obtain an additional data item (PDS ORGANISATION IDENTIFIER (REGISTERING AUTHORITY)) from the Birth Notification information from the Personal Demographic Service (PDS) data held by NHS Digital. This is additional to the PDS data that the applicant already receives from NHS Digital. This is to help improve the linkage of home births to an appropriate Trust/Health Board, since the Trust/Health Board name is not given on the Birth Notification when the baby is born at home, although the majority of home births involve care from the home birth team from a local Trust/Health Board. Applicants will request this field retrospectively initially for the data currently held, and then annually going forward with the annual refresh data extract.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair Team. It was commented that there is a very strong public interest in this amendment, involving patient safety. The Chair was happy to extend the period of data retention of confidential patient information as requested, and to support the additional amendment requests. The Vice Chair commented that the extra data items requested will allow greater granularity to the analysis of mortality relating to patients from different ethnic groups, thus enabling future resources to be targeted to where they are most needed and to relate the results of this audit to specific NHSTrusts/Health Boards.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation of suitable security arrangements via IG Toolkit submission.

Confirmed – Nuffield Department of Population Health, University of Oxford (EE133863-MSD-NDOPH-NDPH) has a confirmed 'Standards Met' grade on DSPT submission 2012/21 and University of Leicester - College of Life Sciences (EE133832-CMBSP) has a confirmed 'Standards Met' grade on DSPT submission 2019/20 (Confirmed by check of the DSPT tracker 09 August 2021**).**

20/CAG/0107 – Childhood outcomes after perinatal brain injury: a population-based linkage study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study from University College London Great Ormond Street Institute of Child Health (UCL GOS ICH) aims to conduct a population-based matched cohort study of children born in England 2008-2020, to investigate differences in long-term health, mortality and educational outcomes in children with perinatal brain injury compared to those without brain injury. Support is currently in place to allow the disclosure of confidential patient information for patients in cohorts 1 and 2 from The Neonatal Data Analysis Unit (NDAU) at Chelsea & Westminster Hospital NHS Foundation trust to NHS Digital for the purposes of the linkage to NHS Digital held datasets, Personal Demographics Service (PDS), Hospital Episode Statistics (HES), Office for National Statistics (ONS) and Mental Health Services Dataset (MHSD), and for the disclosure of confidential patient information for patients in all 3 cohorts from NHS Digital to the Department of Education for linkage to the National Pupil Database.

NHS Digital creates cohort 3, which is a term matched control group. This amendment sought support to include a further variable for NHS Digital to use when creating this cohort - gestation (using ONS birth data). This will help to obtain a more comparable control group.

The applicants also clarify that ONS birth data refers to both ONS birth registration data and ONS birth notification data held by NHS Digital. A combination of ONS birth

registration data, ONS birth notification data, and the Personal Demographic Service data (all held by NHS Digital) will be used to identify the personal identifiers specified in the application for subsequent linkage. These changes do not alter the research design the datasets involved, data flows or the handling/ identification of personal identifiers.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. This amendment is not any more disclosive than the original design, and the CAT raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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: **Confirmed:**

   Due to the number of organisations involved it is the responsibility of University College London Great Ormond Street Institute of Child Health (UCL GOS ICH) as controller, to ensure that all organisations processing confidential patient information without consent 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 a practice. As there are 5+ organisations these will not be individually checked by the Confidentiality Advice Team (CAT).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 18 August 2021**

19/CAG/0185 – Understanding Multidisciplinary approaches and Parental Input in perinatal mortality Review

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The application currently has support in place to allow the incidental disclosure of confidential patient information to the researcher during the observation of perinatal mortality review meetings.

This amendment is to include three further Trusts at which these observations will take place.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The team raised no issues with this amendment in principle.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. 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: **Confirmed:**

- **Hampshire Hospitals Foundation Trust (RN5) has a confirmed 'Standards Met' grade on DSPT submission 2019/20 (**by check of NHS Digital DSPT tracker on 14 April 2021)
- **University Hospitals of Leicester NHS Trust (RWE) has a confirmed 'Standards Met' grade on DSPT submission 2019/20 (**by email to CAT inbox on 23 April 2021)
- **University Hospitals Coventry & Warwickshire NHS Trust (RKB) has a confirmed 'Standards Met' grade on DSPT submission 2020/21 (**by email to CAG inbox on 25/08/2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial by email 10 November 2020**

3. Annual Review Approvals

19/CAG/0077	Neonatal HSV disease in infants under 90 days of age. v1.0.
16/CAG/0058	National Maternity and Perinatal audit
CR28 2014	Study of a Birth Cohort from Hertfordshire
CAG 3-02(a)/2014	Long-term follow-up of ARTISTIC cervical screening trial cohort
20/CAG/0043	Adult social care free text
19/CAG/0137	National Cancer Patient Experience Survey 2019
CAG 8-03(PR2)/2013	UK Register of Fatal anaphylactic reactions
20/CAG/0093	The 2020 Urgent and Emergency Care Survey
17/CAG/0130	Colonoscopic surveillance for familial risk of colorectal cancer
19/CAG/0228	Impact and Accepatibility of Ten Year Risk at Breast Cancer Screening V1

18/CAG/0082	BC-Predict: Providing breast cancer risk as part of the NHS BSP
15/CAG/0119	MBRRACE_UK
ECC 8-05(f)/2010	A National Neonatal Research Database
19/CAG/0109	Suicide by middle-aged men
17/CAG/0096	A population-based study of genetic predisposition to breast cancer
17/CAG/0098	Population based study of genetic predisposition to endometrial cancer
17/CAG/0097	2019 NHS Adult Inpatient Survey
20/CAG/0038	The C3 Study
ECC 7-05(h)/2011	CRANE Database – Epidemiology Register
19/CAG/0136	Acute Leukemia in Pregnancy Registry Study

Signed – Chair

Minutes signed off via correspondence by Dr Tony Calland, MBE, CAG Chair

Date

21/10/2021

Signed – Confidentiality Advice Team

Katy Cassidy

Date

21/10/2021