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

16 July 2021

Present:

Name	Capacity	Items
Dr Murat Soncul	Alternate Vice-Chair	1a, 1b, 1c
Professor Barry Evans	CAG Member	1b
Dr Katie Harron	CAG Member	1a, 1c
Mr Anthony Kane	CAG Member	1b, 1c
Mr Marc Taylor	CAG Member	1a

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	Confidentiality Advisor
Ms Kathleen Cassidy	Confidentiality Advisor

1. New Precedent Set Review Applications – Research

a. 21/CAG/0095 – IMplementation of the Preterm Birth Surveillance PAthway: a RealisT evaluation (including a realist literature scope)

Context

Purpose of application

This application from King's College London set out the purpose of medical research that seeks to identify and understand the features of successful and unsuccessful implementation of the Preterm Birth Surveillance Pathway (PBP).

In the UK, 1 in 13 babies are born pre-term, defined as before 37 weeks of pregnancy. Currently, women at risk of preterm birth receive different care depending on the hospital they're treated at. Some women are offered specialist care in a preterm birth prevention clinic, however many do not receive any specialist care. NHS England has published some guidance on how to standardise care across the UK and this new guidance has developed a pathway called the Preterm Birth Surveillance Pathway (PBP). This pathway states that midwives should assess every pregnant woman for the risk of having a preterm birth by asking questions about her medical history and determining whether she is at high, intermediate or low risk of a preterm birth. If a woman is assessed as being at high or intermediate risk that she should be referred to a special preterm birth prevention clinic. These clinics can offer additional tests and, depending on the results, decide which women may need further help, such as admission to hospital to help prevent the preterm birth.

The applicants will investigate to what extent and in what contexts the PBP is implemented through a realist evaluation, including a realist literature scope (a theory-driven and interpretive type of literature review). The guidance recommending the PBP was published in March 2019 and maternity providers should have implemented this by April 2020. The applicants seek to undertake this research as hospitals begin implementation in order to track the intended and unintended outcomes of pathway implementation, explore implementation facilitators and barriers so sustainability of the pathway is likely, and develop theories on how to improve implementation at different hospitals. A set of recommendations for improving the implementation of the PBP can then be provided.

Hospital staff at participating trusts will access confidential patient information within their IT system and remove patient names and all records for patients who have opted-out. Members of the research team from King's College London, who are not members of the direct care team, will then access the data onsite, under the supervision of a member of the sites' local team in order to pseudonymise the data. The hospital staff will be provided with a record that links the personal information to study participant information number, used to identify duplicated entries and allow data checking/validation. This will be kept locally only on secure NHS servers. Pseudonymised data will be sent securely centrally to King's College London through an established NHS electronic network. Linkage of different datasets will be done centrally based in the study participant information number.

The applicants will also conduct interviews with staff members and patients at each site. Patients will be identified and approached by the clinical care team. Observations of patient care will also be undertaken by the direct care team. The researchers will only have access to confidential patient information for patients who have consented to the sharing of their information. This is outside the scope of the support sought.

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

Confidential patient information requested

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

Cohort	Women who booked their pregnancy between 1st March 2018 – 31st October 2021 at the three participating trusts. 60,900 patients will be included in the data collection. 60 participants in total, half staff and half patients, will be included in the interview arm, which is outside the scope of support.
Data sources	1. Patient records at: a. Leeds Teaching Hospitals NHS Trust b. Homerton University Hospital NHS Foundation Trust c. Yeovil District Hospital NHS Foundation Trust
Identifiers required for linkage purposes	1. NHS Number 2. Hospital ID number 3. Date of birth
Identifiers required for analysis purposes	No identifiers will be retained for analysis.

Confidentiality Advisory Group advice

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

Public interest

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

Scope

The CAG noted that the terms 'pseudonymisation' and 'anonymisation' were used inconsistently and possibly inaccurately in the application. The applicants intended to generate an encrypted version of the NHS number, the hospital number, and date of birth, which can then be used to

link the data together. Members agreed that this meant that data was more likely to be considered to be pseudonymised rather than anonymised.

Members asked that further clarification was provided on the pseudonymisation and anonymisation processes that would be followed.

The applicants also state that the linkage of different datasets undertaken at King's College London will be conducted based on the pseudonyms generated. This suggested that the "pseudonymised data" held by King's College London is identifiable. Members requested clarification on the identifiers needed to conduct the linkages within King's College London and an explanation provided on how the linkage will be undertaken if the re-identification key is held within the participating trusts only.

The specific datasets that will be linked to within King's College London were also not specified. Members agreed that the specific datasets needed to be named. Further information also needed to be provided on the variables that would be extracted and what is meant by 'maternity' and 'neonatal' admin and routine datasets. The data flows also need to be made clear in the data flow diagram.

Practicable alternatives

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

- **Feasibility of consent**

The applicants explained that the data collection aspect of the study would be conducted retrospectively, including a period before implementation of the PBP and a period after.

- **Use of anonymised/pseudonymised data**

The applicants explained that pseudonymisation of the data is a complex task, involving the calculation of maternal age in early pregnancy, estimation of index of socioeconomic deprivation from full postcode and complex formulae to allocate a study ID to the research participant.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Posters will be displayed at each site. Email and telephone contacts were provided on these posters for patients to opt-out. Email and telephone contacts were also given for the Chief Investigator and Student Researcher for patients to contact with queries.

Each site will hold an opt-out register within the site file, to record the details of women who request that their information is not shared with the research team.

Additionally, each site will confirm the list of those participants who have signed the national data opt-out register. The details of all these women will be removed by the local site team before the research team have local access to the data for the purpose of performing the linkage and anonymisation.

The applicants will also post on social media, for example the Mumsnet pages local to the three participating sites. Draft text was provided. The study protocol will also be published in an open-access journal, available to the public. The study will also be registered with the ISRCTN, in a record which is publicly available.

The CAG noted that the patient notification materials will need revisions to address the use of 'pseudonymisation' and 'anonymisation' so that they are used consistently and in line with the responses given to address the queries under “Scope.”

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants engaged with two Patient and Public Involvement Groups when developing the proposal. These were the King’s College London PPI Preterm Birth group and a second PPI group that included those with no personal preterm experience. A PPI workshop was also arranged, which included relevant charities and London Maternity Voice Partnership members.

Both PPI groups, alongside the charities TAMBA (now known as Twins Trust) and Bliss provided feedback on how to make the Plain English summary clearer and more accessible. The Bliss and Tommy’s charities have also both written letters of support for the IMPART Study, believing that evaluation of the preterm birth surveillance pathway is required.

Throughout the study, meetings will be held with the Project Advisory Group (which will include up to 4 PPI women, charity representatives, and the IMPART study group). The applicants explained that consulting 4 women minimizes the PPI burden falling on any individual participant and improves the chances that PPI sessions are quorate. As realist evaluation is an iterative, non-linear process, regular PPI input throughout the study will be crucial to honing the research at each stage. At the end of the study, a dissemination plan will be co-developed with the Project Advisory Group.

Since completing the IRAS form, the applicants have also undertaken two Project Advisory Group meetings. These include five women/PPI members. All women have used maternity services recently (within the last 2 years). Three of the women have experience of preterm birth. Two of the women have been pregnant once, three have been pregnant more than once. Two

of the women describe themselves as White British, one as Mixed Race (White and Black Caribbean), one as Black Caribbean and one as Black African. The five women live in different areas of England (the range includes Manchester, Birmingham, London, Kent and Sunderland).

The study has been discussed in more depth (with a smaller group with more time) over Zoom with these women. This has been through a combination of PowerPoint presentations, open discussions, and questions/answers. No concerns were raised regarding the acceptability of analysing the routinely collected hospital and admin activity data without consent. They did note that they felt reassured that the data would be pseudonymised before being analysed or leaving the local sites.

Exit strategy

A pseudonymised dataset only will be extracted from participating trusts and transferred to King's College London.

The CAG agreed that further details needed to be provided on the exit strategy and when confidential patient information will no longer be processed. This deadline for processing needs to align with the deadline for patients' objections, 01 July 2022. The research data that needs to be retained for 10 years needs to be specified.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Further clarification needs to be provided on the pseudonymisation and anonymisation processes that will be followed.

2. Further information on how the linkages conducted within King's College London will be carried out is needed:

    a. The identifiers needed to conduct the linkages within King's College London need to be clarified and an explanation provided on how the linkage will be undertaken if the re-identification key is held within the participating trusts only.

    b. The specific datasets that will be linked to within King's College London need to be named.

c. Further information also needs to be provided on the variables that will be extracted.

d. The meaning of maternity' and 'neonatal' admin and routine datasets needs to be explained.

e. The data flows also need to be made clear in the data flow diagram.

3. The patient notification materials require revisions to address the use of 'pseudonymisation' and 'anonymisation' so that they are used consistently and in line with the responses given to the queries above.

4. Further details need to be provided on the exit strategy;

   a. Clarification needs to be provided on when confidential patient information will no longer be processed. This deadline for processing needs to align with the deadline for patients' objections, 01 July 2022.

   b. The research data that needs to be retained for 10 years needs to be specified.

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

Specific conditions of support

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

1. Favourable opinion from a Research Ethics Committee. **Confirmed 30 June 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:

   The NHS Digital **2019/20** DSPT review for Leeds Teaching Hospitals NHS Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (27 July 2021).

   Pending: The NHS Digital **2019/20** DSPT reviews for Homerton University Hospital NHS Foundation Trust and Yeovil District Hospital NHS Foundation Trust.

b. 21/CAG/0102 - Barts Myocardial Infarction with Non-Obstructed Coronary Arteries Registry

Context

Purpose of application

This application from the Queen Mary University of London set out the purpose of medical research that seeks to assess the safety, efficacy and feasibility of further investigations in patients diagnosed with MINOCA among all patients with coronary artery disease.

The introduction of primary angioplasty over the last 15 years has radically improved patient outcomes for those suffering an acute myocardial infarction (AMI). However, the system wide availability of prompt investigation has reviewed an important group of patients where progress has stalled, their diagnosis is unclear and therapeutic approaches are uncertain. Myocardial infarction with non-obstructive coronary arteries (MINOCA) is found in 1 – 13% of all patients with a clinical diagnosis of AMI. MINOCA represents a diagnostic challenge with limited current guidance on how to investigate and treat the condition. Cardiac Magnetic Resonance Imaging (CMR) plays a pivotal role in cardiac morphological, functional assessment and tissue characterisation, and therefore has the potential to identify underlying aetiologies and aid a final diagnosis in MINOCA. Small, retrospective case series have suggested that CMR can provide a definitive diagnosis in 63-72% of patients. These previous studies also suggested that only 5-15% of patients with MINCOA had had an MI.

The applicants seek to create the Barts-MINOCA registry, a single-centre, retrospective observational registry based at Barts Health NHS Trust. The aim is to develop understanding of the characteristics and outcomes of patients with MINOCA and troponin rise without diagnosis. All patients aged>16 years old with MINOCA or an unknown cause of troponin rise, regardless of severity, referred to Barts Health NHS Trust will be included in this study. Confidential patient information will be prospectively collected from clinical database and systems (such as PACS for imaging data, CRS for blood results). The data is stored at Barts Health NHS Trust on secure NHS clinical servers and will be accessed only by named members of the clinical team. Data is entered onto the database by clinical team members and is used directly for patient care. Patients will not be contacted at any point to obtain data specifically for research purposes. As the majority of information on patient outcomes will not be available locally, the applicants will disclose confidential patient information to NHS Digital for linkage of HES and ONS datasets.

A recommendation for class 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 aged 16 years and over who either have a diagnosis of MINOCA or patients who do not have a clear cause of troponin rise. 2500 patients will be included.
Data sources	2. Electronic and paper records held at Barts Health NHS Trust 3. HES and ONS datasets at NHS Digital
Identifiers required for linkage purposes	4. Name 5. NHS Number 6. Hospital ID number 7. Date of birth 8. Postcode – District level
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – district level 4. Gender

Confidentiality Advisory Group advice

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

Public interest

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

Practicable alternatives

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

- **Feasibility of consent**

The applicants explained that, as the study is retrospective, seeking consent from patients would be impracticable as many patients would be deceased. The applicants also noted the potential risk of bias. The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for NHS Digital to link data from Barts Health NHS Trust to HES and ONS datasets at NHS Digital. This could not be undertaken in any other way.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants provided a poster (local poster for dissent(KR)) which would be displayed in clinical areas.

The applicants explained that any dissent recorded in patient notes would be respected.

The National Data Opt-Out would be applied after the compliance deadline or after Barts Health NHS Trust declare compliance, whichever date is earlier, by using the MESH opt-out system.

The CAG noted this information and raised no queries.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public are considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants explained that they had conducted a survey of patients with MINOCA via a Barts Heart Centre patient and public involvement group. Patients did not object to the following up of their progress via local and national systems.

The applicants provided a poster (local poster for dissent(KR)) which would be displayed in clinical areas. This provided telephone, email and postal contacts for dissent.

The CAG noted this information and raised no queries.

Exit strategy

The applicants anticipate that the linkage of data at NHS Digital will be completed within 6 months of the start of the project. The CAG agreed that the date that the confidential patient information collected for the project will be deleted by the research team needed to be confirmed.

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

1. The date that the confidential patient information collected for the project will be deleted by the research team needed to be confirmed.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 20 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 **2019/20** DSPT review for Barts Health NHS Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (by check of the NHS Digital DSPT tracker on 28 July 2021).

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

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)	9. Name 10. Date of birth, 11. NHS number, 12. gender, 13. Full address including postcode
Identifiers required for linkage purposes	1. NHS Number 2. Postcode 3. Date of birth
Identifiers required for analysis purposes	5. Gender 6. Ethnicity 7. 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

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

Public interest

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

The Members were agreed that this application constitutes an appropriate medical purpose that is in the public interest.

Practicable alternatives

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

- **Feasibility of consent**

Consent will be implied for the return of the questionnaire. It is not practicable for the direct care team to consent for sending out the survey, partly because of the retrospective nature and partly due to burden on the clinical team. Applicants also wish to be able to contact more than 1/5 of the population, as in the original BRIGHTLIGHT study, and this is supported by feedback from the patient and public involvement undertaken.

Justification as to why it is not practicable to take consent for the linkage (considering all participants are returning a questionnaire), is that obtaining written informed consent for the linkages would require asking young people to include identifiable information alongside the return of the survey, which would contradict the survey responses being anonymous – this could be a deterrent to participation or to honest disclosure, which would greatly bias the results. Additionally implied consent is not appropriate for linkage to be undertaken, so alternative to 's251' would be a paper consent form, however if asking for consent and form not returned, these individuals would have to be excluded as non-responders, which would reduce the effectiveness of the study.

The Group were content with the justifications provided, and agreed that consent was not a practicable alternative for either element of the application.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to send invitation letters to people, and also required for linkage. The data is pseudonymised at the earliest opportunity. Members were assured this could not be undertaken in a less disclosive manner.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'.

This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Prior to the first disclosure

A study specific opt-out is offered prior to contact details being sent from NHS Trusts to Quality Health. To ensure young people have the option of not having their details sent to Quality Health, posters will be given to each TYA MDT and the hospitals they link to, which will have the contact details of the TYA MDT coordinator, so they can opt out of this disclosure. All 13 hospitals also have other ways to communicate with young people via social media channels, and this information will also be circulated via these mechanisms. An information sheet for healthcare professionals will be sent to the TYA lead in each hospital that joins the TYA MDT so they can make the clinical teams aware of the study. This advises clinical teams to inform young people about the study in case they do not see the poster to optimise their opportunity to opt-out of receiving an invitation to participate.

The Committee were content with the type of notification and opt-out options surrounding the initial disclosure, however, they did request an updated poster be provided with some details altered. It was commented that the poster should clearly explain the linkage involved, and the statement "*Quality Health... will only use your details to carry out the survey"* should be altered, as this is technically not correct – details will also be sent to NHS Digital to undertake linkage. Noting that these disclosures are happening at a later date, and all eligible people will receive further information, however, the Committee felt that this should still be clear on the initial poster.

Communication to invite people to fill in survey, and inform about linkage

A letter will be sent to the cohort alongside a participant information sheet (PIS), and a questionnaire. These documents invite the participant to return the survey, and explain that they are receiving the letter with 's251' as the legal basis for writing to them. Linkage is explained, and if participants do not wish for their data to be linked with NCRAS, they can opt-out. The local TYA MDTs will be asked to engage their internal social media groups for TYA to remind young people to return their surveys. Applicants will also utilise relevant charities such as Teenage Cancer Trust to post photographs of the survey and the envelope they arrive in on their social media reminding young people to open, complete and return it (our previous work indicated young people may ignore the envelope as it looks 'official'. Quality Health have a contract with Language Line so young people have the option of completing the survey through a telephone interview in the language of their choice.

The National data opt-out will be applied, and a study specific opt-out is also offered for the linkage with NCRAS data.

The CAG were broadly content with the notifications and opt-out options provided, however, they noted that the cover letter and subsequent reminder letters did not mention the linkage at all, and did not provide an email address for opting out of repeated contacts. The linkage is described as part of the actual survey which also offers an opt-out option via email and telephone, however, the Members felt that this should also be described on the survey cover letter and additional reminder letters. Therefore, the survey cover letter, reminder letters and

other relevant notifications should be amended to consistently and clearly refer to the linkage and give details as to who to contact to register objections including an email address for opting out of repeated contacts and or linkage.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public are considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants have undertaken ongoing work with patients and the public, since 2008. The original BRIGHTLIGHT application was developed with a young advisory panel (YAP). Applicants asked about methods of recruitment to different types of research, and the YAP reported that direct approaches through the mail for surveys was acceptable. Young people in the YAP were frustrated that options to take part in research via traditional methods were restrictive. They were therefore supportive of the use of confidential patient information without consent for the purposes described, in order to give more people the option to take part. Two YAP members have joined the research team for the current BRIGHTLIGHT_2021 application. An initial virtual workshop was held with existing members of the YAP, to present plans for BRIGHTLIGHT_2021. Eight YAP members worked on the survey. New members who have more recent experiences of care are currently being enrolled. The Facebook page also has a response rate of over 50% of young people responding to messages about BRIGHTLIGHT_2021 queries and invites to meetings. Attendance at online meetings has been equivalent, if not higher to our traditional face-to-face methods. Further meetings are planned throughout the study.

The CAG were content that sufficient patient and public involvement had been undertaken, specifically discussing the use of confidential patient information without consent.

Exit strategy

The exit strategy for support for the use of confidential patient information to send out surveys is the return of the survey via implied consent. However, identifiable information will need to be retained under ‘s251’ by Quality Health to undertake the linkage. Quality Health will retain identifiable information securely until the NCRAS data for 1 year follow-up is updated (approximately 2023). Quality Health will destroy all data once they have transferred to NHS Digital. NHS Digital will delete all identifiable data after it has been linked and modified, in approximately 2023. Support will be required until this point, at which time point the exit strategy is anonymisation. The Committee were content with this exit strategy.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

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

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"*.

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.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support

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

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

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

Minutes signed off as accurate by correspondence from Dr Murat Soncul, CAG Alternate Vice-Chair		*01 October 2021*
Signed – Officers of CAG		Date
Caroline Watchurst		01 October 2021
Signed – Confidentiality Advice Team		Date