Minutes of the meeting of the Confidentiality Advisory Group

24 March 2022 – held via Zoom

Present:

Name	
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Dr Malcolm Booth	CAG member
Mr Tony Kane	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Ms Rose Payne	CAG member
Professor Sara Randall	CAG member
Mr Dan Roulstone	CAG member
Ms Clare Sanderson	CAG alternative vice-chair

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Michael Pate	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Mr Ioan Wigley	Observer
Mr Liam Hutchinson	Observer

1. Introduction, apologies and declarations of interest

Ms Rose Payne, CAG Member, declared a conflict of interest with this application, as a participant in the TEDS study. Ms Payne did not participate in the development of the recommendation provided by the CAG.

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care has not yet provided a response to the advice provided by the CAG in relation to the **24 February 2022** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **24 February 2022** meeting applications.

3. Resubmitted New Applications

a. 22/CAG/0038 - Twins' Early Development Study (TEDS) Medical Record Linkage

Context

Purpose of application

This application from King's College London (KCL) set out the purpose of medical research that seeks to investigate how genetic and environmental factors influence development, with a particular focus on psychological development and mental health.

The Twins Early Developmental Study (TEDS) is a longitudinal study which recruited over 16,000 twin pairs who were born in England and Wales between 1994 and 1996. Approximately 10,000 families are still actively engaged. The twin pairs have been assessed across cognitive, emotional and behavioural domains from early infancy into adulthood. Genotyping data is available for 10,346 individuals. The applicants now intend to link the already collected data with data from patients' medical records, obtained from NHS Digital, in order to build predictive longitudinal, genetic and clinical models of mental health outcomes, such as disorder risk and response to treatment. The applicants noted that it was important to gather information at this stage in patients' lives, as new mental health conditions often peak in the mid-twenties.

The data flow is separated into three pathways; obtaining up to date contact details for participants, the secondary care linkage undertaken by NHS Digital, and linkage to primary care data undertaken by the GP practices of patients included in TEDS.

In pathway one; confidential patient information from the TEDS dataset, held in the South London and Maudsley Clinical Data Linkage Service (SLAM CDLS) Safe Haven, will be disclosed to NHS Digital for linkage to the Personal Demographics Service (PDS), in order to obtain patients address and GP registration information. The linked dataset will then be returned to the TEDS research team. The research team will then send information about the study and how to opt-out to patients.

In pathway two; confidential patient information from the TEDS dataset, excluding those who opted-out, will be disclosed to NHS Digital for linkage to the Hospital Episode Statistics (HES), Mental Health Services Dataset (MHSDS) and the Improving Access to Psychological Therapies (IAPT) dataset. NHS Digital will then send a linked dataset, which has been pseudonymised by removal of patients NHS number, name, address and date of birth, to the TEDS research team. The research team will use the TEDS ID to link the dataset to the existing TEDS dataset.

In pathway three; confidential patient information will be disclosed from the TEDS dataset to patients GPs, firstly to seek GPs assent to access the GP health records for TEDS participants and then for linkage to their primary care record. The data from GPs will be pseudonymised and returned to TEDS with the TEDS ID as the identifier.

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	Sets of twins born between 1994 and 1996 who were enrolled into TEDS. 26000 patients will be included.
Data sources	1. TEDS database at King's College London/ SLaM CLDS Safe Haven 2. HES and MHSDS datasets held by NHS Digital 3. IAPT service data held by NHS Digital 4. Locally held information contained in the lifetime primary care electronic patient record, provided by participants' GP surgery
Identifiers required for linkage purposes	1. Name 2. NHS number 3. GP Registration 4. Date of birth 5. Postcode – unit level
Identifiers required for analysis purposes	1. Gender 2. Occupation 3. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within

the remit of the section 251 of the NHS Act 2006. The CAG agreed that there was a substantial public interest in maintaining the integrity of this important application.

Scope

As part of the response to the previously deferred application, the applicant was asked to clarify the legal basis for the retention of confidential patient information. *Condition 1;* '*A legal basis needs to be provided for the continued holding under the common law of previously collected TEDS data, as 'reasonable expectation' is not sufficient. This legal basis needs to cover the continued holding of information for deceased patients, those who had disengaged from the TEDS project and those who had reached the age of 16 but were still included in the project under their parents/guardians consent, rather than their own.'*

Regarding this re-submission, the applicant has provided legal advice from the legal team internally at Kings College London. The CAG noted that view of the applicant that the legal basis for retention of this data, under common law, is consent, for all patient groups including the deceased, disengaged people, and those who are over 16, but are included under the initial consent of their parent/guardian. On this basis the applicant is not requesting 's251' support for the retention of this data, but only to link to PDS, HES, MHSDS, and IAPT at NHS Digital and GP records from individual practices, for all the groups the applicant believes is appropriate. On this basis, the Members noted that the additional justification provided by the applicant regarding the confidential patient information not being classified as such, is moot.

The Members noted that as part of the application, the applicant has suggested not disclosing confidential patient information to NHS Digital to link with PDS and other datasets regarding the few individuals who signed up to TEDS initially, but never completed any data. The CAG consider that the applicant can exclude this group, if they feel it is appropriate.

The CAG suggest that the applicants should reaffirm the continued holding of identifiable information within their next annual newsletter to ensure all participants are aware of this, reporting on this at the first annual review.

The CAG note the view of the applicant that consent is the legal basis for retention of this data for all categories of individual, including those who were included only with the consent of their parent/guardian, and neither the parent or participant has been in contact with TEDS since being initially included. The applicant has provided information which shows approximately 3-4000 participants have not had any contact at all since becoming 16, and some from when they were very young. The Members therefore suggested that the view of the applicant that consent is the legal basis for retention, is strengthened by consenting these individuals (no TEDS contact post age 16) to the continued holding of data at future waves, alongside consent to linkage, as applicants

have noted they are willing to use consent as an exit strategy for linkage where possible, and it should be possible to ensure this is undertaken as part of the same fair processing work.

Practicable alternatives

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

- **Minimising flows of identifiable information**

As part of the previous deferred outcome for 21/CAG/0057, the CAG had requested confirmation that no free text would be obtained, with information obtained from GP and IAPT records of particular concern. The applicant had confirmed that no free text information would be obtained. As part of this response to the previous deferral, the applicant has provided conflicting statements as part of the application documents regarding whether free text would be collected from GP records, despite responding that it would not be. Therefore, the CAG asked the applicant to clarify during the review. The CI clarified that no free text records would be collected from GP records, and the CAG was content with this clarification.

The Members also wondered if any items of confidential patient information were inadvertently collected as part of questionnaire responses, such as first names of the twins. This was also clarified with the CI as part of the review, who confirmed that all survey data contains only ID numbers, and never names of the twins. The CAG were content with this clarification.

- **Feasibility of consent**

As part of the response to the previously deferred application, Condition 2, the applicant was asked to **'***Consider whether consent can be sought from those who are still actively engaged in TEDS and whether support can then be sought only to link and anonymise data for those who have disengaged. If this approach cannot be implemented, justification needs to be given as to why not.'*

The applicants explained the difficulty in determining who is considered engaged or disengaged from TEDS, given approximately 50% respond to any one invite, but this is not the same 50% each time. A consent process would also involve writing to approximately 15,000 of those participants who may be considered 'engaged' to seek consent, and risk losing about 50% of the sample if the ICO non-responder guidance is followed, as non-responders would have to be considered dissented. As such the applicants argue that doing as suggested is impracticable. The CAG accepted this justification.

The applicant has indicated a willingness to use consent as an exit strategy for linkage, and suggested that over the next 5 years of contacting participants for future waves, they could include a request to consent for future medical linkages. Upon consent, this would remove an individual from reliance of Regulation 5 support as the legal basis. The CAG agree with this suggestion, and it is a condition of support.

As part of the response to the previously deferred application, Condition 3, the applicant was asked to *'Consider whether the fair processing campaign could lessen the rate of attrition and provide feedback of the researchers views on this.'*

The applicants do not consider this to be reasonably likely, and the CAG accepted the reasoning provided.

As part of the previous deferred outcome, the applicants expected that 60% of GPs contacted would not agree to disclose patient records. The CAG recognised that this would have a lesser impact on bias but was still a significant rate of attrition. The applicant was asked, Condition 5, to '*Provide further details on how the process of obtaining patient records from GPs would be managed, particularly how the rate of attrition would be managed.'*

The applicants note that this reference is not correct, and it is 40%. The methodology used to collect GP data is based on the ALSPAC PEARL method of collecting GP medical records. These applications have previously been supported by CAG (ECC 1-05(b)/2012), 15/CAG/0175, 15/CAG/0176, 15/CAG/0177) using similar methodology to that proposed here. The Committee accepted this explanation, and the deferral point is resolved.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required firstly to contact patients with information about the further data collection and provide an opportunity to opt-out. Confidential patient information for those who did not opt-out would then be used to link the TEDS cohort to HES, MHSDS, IAPT datasets at NHS Digital and to GP held data.

'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 explained that they would follow the methodology of ALSPAC and TwinsUK by sending out a Data Linkage Decision form to participants addresses. If a participant opted-out, this decision would be recorded on an electronic database and the paper copy archived. Any opt outs received via email would also be stored. Email and telephone contact details were provided, alongside a postal address to return the form.

Data will be extracted on a periodic basis, most likely annually. Prior to a data extraction, TEDS will inform the CDLS of any participants who have changed their consent status and ask for them to be excluded from the extraction. Where a decision status is changed via the opt out scheme, these cases will not be included in the next extraction.

The applicants will use social media (Facebook, twitter, etc) to spread awareness of the further data linkages. TEDS will update the participants on the use of linkage data and the findings of the research by e-newsletters, social media posts and an annual postal newsletter.

Once the patient notification has been sent, participants will have one month to register an opt-out. If no response has been received within 2 weeks of the initial sending of the pack, then a reminder will be sent. The applicants explained that, should an opt-out request be received after the deadline, then the participants' data will be removed during the data cleaning process.

The CAG again agreed that the patient notification system was comprehensive and the patient notification documents were well-crafted.

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 in consultation a group of TEDS participants who are still actively engaged with the study. The applicant provided documents that describe the discussions around concerns the participants had, such as concerns around data security, completeness of records and re-contacting patients, and possible solutions. Details were also provided on the discussions around the language used in information about the study. The applicants also provided a document which detailed the ways in which they stayed in touch with participants.

Since the original CAG submission, the applicants have undertaken remote consultations with participants. The applicants noted that TEDS had experienced a significant attrition of participants over time. The applicants wanted to obtain medical records for all those who were enrolled in TEDS originally, even if they had not participants in subsequent waves of assessment. To explore this issue, the applicants

had contacted a small group of twins who had recently rekindled participation in the study. None of this group had actively participated since the age of 18 and had been inactive since the age of 4. A questionnaire was posted on social media for any TEDS participants to complete. The same questionnaire, including additional options to provide free text responses, was sent to the recently traced cohort. Prior to completing the questionnaire, participants read a brief description of the proposed using language agreed with the consultation panel, then assessed knowledge about medical record linkage, opt-out, data security, and trust in the TEDS team.

The applicants also conducted further PPI with active and inactive participants, where participants were provided with the revised medical record linkage information leaflet and asked to provide feedback. They also answered questions about the data linkage via an online survey. The Committee commended this excellent use of seeking inactive participants for their views.

The feedback from the above was largely supportive, with some minor concerns and uncertainty over whether the benefit outweighed the risk expressed. One Patient and public involvement participant noted struggling with the notification materials due to dyslexia, and the applicant will work on producing an animated version of the information in response to this feedback. The Committee also commended this action.

The patient and public involvement carried out appears to be comprehensive and detailed, and explored the use of confidential patient information without consent.

Data Access Committee

Only fully anonymised data will be made available to researchers. The policy on how the application process to use the data was provided.

Members noted that the Data Access Committee was comprised of internal staff only. As part of the previous deferred outcome, Condition 4, the CAG felt *'An external person and a lay member need to be included on the Data Access Committee.'*

As part of the response to deferral, this point seemed not to have been considered, and therefore the Committee queried the CI regarding this point during the review. The CI confirmed that lay individuals would be included on the Data Access Committee, and the CAG were content with this verbal confirmation.

Exit strategy

The applicant has indicated a willingness to use consent as an exit strategy for the linkages, and suggested that over the next 5 years of contacting participants either for a specific fair processing campaign, or a request to consent for future medical linkages could be included in future waves of TEDS contacts. Upon consent, this would remove

an individual from reliance of Regulation 5 support as the legal basis. The CAG agree with this suggestion, and it is a condition of support.

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 actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

Request for further information

1. Please provide the Favourable Opinion from a Research Ethics Committee once this is in place, as per standard condition of support.

Specific conditions of support

The following sets out the specific conditions of support.

1. Support is provided for 5 years from the date of final support, to allow the applicant time to complete the exit strategy, and gain consent from participants to undertake the proposed linkages. A duration amendment will be required at this time, if an extension of support is required. Please report on the progress of consent for linkage at each annual review
2. Please reaffirm the continued holding of identifiable information within the annual newsletters to ensure all participants are aware of this, reporting on this at the first annual review.

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

4. 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 **South London and Maudsley NHS Foundation Trust (RV5) and NHS Digital** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 29 March 2022)

   Regarding participating GP surgeries; due to the number of organisations involved it is the responsibility of King's College London, as controller, to ensure that participating practices 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.

4. New applications

a. 22/CAG/0051 – Our Future Health

Context

Purpose of application

This application from Our Future Health Ltd set out the purpose of medical research to create a research tissue bank for use in research into early detection of disease.

The aim of Our Future Health Ltd research programme is to speed up the discovery of new methods of early disease detection, and the evaluation of new diagnostic tools, to help identify and treat diseases early, with the hope that this will lead to better patient outcomes.

Our Future Health aim to recruit up to 5 million adults from across the UK to create a cohort of people who have consented to participate in the research. In addition to being asked for permission to link their personal health data to other health-relevant data, participants will be asked to: provide biological samples and complete questionnaires on recruitment; agree to re-contact for ongoing biological sampling and questionnaires and consider taking part in further research studies; and consider being offered personal health information arising from the research. Potential participants will be identified and contacted in various ways, including: identification by staff in primary and secondary care, by NHS blood donation, direct recruitment and survey based sampling. Participants in existing research studies will also be contacted about this study. These methods of recruitment are outside the scope of the support sought, as confidential patient information will be processed only by those with an existing legal basis.

The applicants will also identify and contact patients in England via DigiTrials. Approximately 3 million patients will be identified and contacted, with an assumed response rate of 5%, around 150,000 patients will be recruited. The processing of confidential patient information by NHS Digital employees to generate the cohort to be invited into the research programme is covered by Directions (specifically the Pilot NHS DigiTrials Recruitment Support Services Direction 2021). Support is required to allow the disclosure of confidential patient information from NHS Digital to a contracted mailing supplier, APS Group. APS Group will be provided patient names, full addresses and postcode and invitation code. Patients will be sent either; an invitation letter, an invitation letter plus a short leaflet, or an invitation letter plus the full participant

information sheet. Differences in the response rates from these three methods will be evaluated to inform which will be used in the long term. Interested patients will be directed to the Our Future Health web-based system, where they can electronically consent to participate. Only at this point will Our Future Health receive patient information.

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

Confidential patient information requested

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

Cohort	All patients aged 18 and who meet other inclusion or exclusion criteria to enable representative shaping of the overall Our Future Health participant base.
Data sources	1. Personal Demographics Service at NHS Digital
Identifiers required for linkage purposes	1. First name 2. Surname 3. Full Address 4. Postcode
Identifiers required for analysis purposes	Any identifiers retained will be done so with patient consent.

Confidentiality Advisory Group advice

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

Public interest

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

Selected patients will be contacted by the mailing contractor, APS Group, to seek consent. Patient participation well then proceed on a consented basis. The CAG agreed that seeking consent prior to making contact was not feasible.

- **Use of anonymised/pseudonymised data**

APS Group, the mailing contractor, require access to confidential patient information in order to send the invitation letters and information about the study to potential participants. The application activity could not be carried out 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 will undertake to inform the general public about the programme before the data extraction takes place. The applicants plan to carry out extensive communication and awareness activities in the regions in which people will be invited e.g. for 2 weeks, 4-6 weeks before invitations are facilitated. The applicants provided a comprehensive communications plan which set out various methods of promoting the study, included radio, press and social media promotion.

Online and telephone options to express dissent will be provided. The on-line option will be incorporated on the NHS Digital public facing website, and the link will be referenced on the Our Future Health public facing website to maximise the opportunity for those who hear of the programme through local publicity and choose to opt-out. A centralised telephone number will be primed to support calls from patients.

The National Data Opt-Out will be applied by NHS Digital when running the query to exclude those who have chosen to opt-out of the use of their data for planning and research purposes. These individuals will not be invited to take part in the programme.

Immediately prior to sending the lists to the mailing contractor (the APS Group) final checks will be run to remove any new opt-outs, sensitivity flags and to remove anyone who has recently died.

Patients identified as eligible to take part will be sent an invitation letter. Reminder letters will not be sent.

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 worked with Claremont, a behaviour change communications agency to involve members of the public in the design of the project and the development of public-facing materials. The applicants provided details on the meetings held to discuss the participant information sheet and consent form.

NHS Digitrials have also undertaken patient involvement and engagement. NHS DigiTrials have a dedicated Co-Development Panel comprised of 10 attendees who were recruited via public advertisement and structured interviews, to provide a broad representation of regions of England, age, gender and ethnicity. They have varying degrees of experience and interest in clinical trials. The panel have been consulted to test the acceptability of NHS Digital using confidential patient information to identify a cohort and disseminate this to a third-party mail house, for the purpose of inviting an individual to take part in research. Feedback has been supportive.

To verify findings and further test acceptability of the NHS DigiTrials Recruitment service, a survey is being commissioned to administer to 6,000 members of the public, followed by deeper exploration through focus groups and one-to-one interviews facilitated by a Behavioural Scientist.

The CAG noted that the patient and public involvement conducted was of good quality and raised no queries in this area.

Exit strategy

The applicants confirmed that the data for all patients contacted will be deleted by APS within two weeks of sending the invitation letters. No further letters or reminders will be sent. The CAG noted this information and raised no queries.

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: 29 March 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 **2020/21** DSPT review for **APS Group Ltd** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 24 March 2022)

b. 22/CAG/0050 - A Multi-Centre Randomised Controlled Trial of the Clinical and Cost Effectiveness of Pre-Hospital Whole Blood Administration versus Standard Care for Traumatic Haemorrhage

Context

Purpose of application

This application from NHS Blood and Transplant set out the purpose of medical research that seeks to determine whether pre-hospital leukocyte-depleted whole blood transfusion is better than standard care in reducing the proportion of participants who experience death or massive transfusion.

More than 5,400 people die every year in the UK as a result of major trauma. Uncontrolled bleeding accounts for a large proportion of these deaths, with approximately 20% occurring in the first 24 hours and 40% occurring within the first 30 days. The overall cost to the NHS for managing major trauma is estimated to be £150 million per annum and blood transfusion makes up around 12% of this cost. Blood transfusion is a life-saving treatment in the management of bleeds and is typically delivered through different blood components. These components, red blood cells, plasma and platelets, are derived from whole blood donation and stored in separate bags. Carrying several different blood products can cause problems, such as additional weight in kit bags, and transfusing multiple blood products at scene may delay transport to hospital. Most UK Air Ambulance Services carry red blood cells and plasma to transfuse pre-hospital. However, a pre-hospital transfusion strategy has not been established and practice varies across the country. This trial aims to investigate if carrying and transfusing two units of whole blood instead of four units (two red blood cells and two plasma) leads to better outcomes for patients and reduces costs.

Randomised boxes containing either 2 units of whole blood or 2 units of red blood cells and 2 units of plasma, will be prepared in advance by the Transfusion Laboratory Teams and supplied to the participating Air Ambulance Services. If they attend a patient who has suffered major trauma and requires blood transfusion, the team will open the trial intervention box and administer the contents to the patient, in accordance with standard local blood transfusion protocols. The time that the box was opened will be recorded and referred to as the randomisation time for the purposes of follow-up data collection. The Air Ambulance team will notify the team at the receiving hospital if the patient has been enrolled into the SWiFT trial and provide the relevant randomisation number. Patients will be followed up for up to 90 days post-randomisation. Additional data, which is routinely collected by the Trauma Audit and Research Network (TARN) and the Intensive Care National Audit and Research Centre (ICNARC), will also be obtained. Consent cannot be sought at the time of recruitment to the trial, as the patients will not have capacity. Patients will be enrolled under the emergency provisions of the Clinical Trial Regulations and consent sought, where possible, once capacity is regained. Once informed consent has been obtained, confidential patient information will be securely provided to NHSBT CTU by the Research Team. This will allow for linkage to the TARN and ICNARC datasets. Support under Regulation 5 is sought to include patients who could not be consented, due to death or to being discharged prior to consent being sought.

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 0 years and above who are attended by a participating Air Ambulance Service (AAS) clinical team and required pre-hospital blood transfusion to treat major traumatic haemorrhage. The applicants anticipate that 848 patients will be recruited.
Data sources	1. Intensive Care National Audit and Research Centre (ICNARC). 2. Trauma Audit and Research Network (TARN)
Identifiers required for linkage purposes	1. NHS number 2. Date of birth
Identifiers required for analysis purposes	1. Date of death 2. 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.

Scope

The CAG agreed that support would be recommended for patients who died or were discharged before they could be approached for consent.

Members noted that it was unclear in the application whether the applicants were seeking support to include patients who had been given information about the study and/or a consent form, but who had been discharged before the signed consent form was returned.

If patients were approached about the study and did not give consent before they were discharged or died before consent could obtained, they needed to be considered as dissenting to take part and could not be included under support. This was in line with guidance from the Information Commissioner's Office that non-response to a request for consent is to be considered as dissent.

The CAG requested confirmation that the applicants would ensure that patients were approached with information about the study as soon as possible after it had been determined that patients had the capacity to consent. For patients who lacked capacity, their legal representative needed to be approached as soon as possible with information about the study and the request for consent.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available. The CAG agreed that the application had a medical purpose and was in the public interest.

- **Feasibility of consent**

The research teams at participating trusts will obtain consent from patients or their legal representative as soon as possible. Some patients will die or be discharged before they can be approached for consent. The scope of support will cover this group of patients.

The CAG agreed that support would be recommended for patients who died or were discharged before they could be approached for consent. For patients who lacked capacity, their legal representative needed to be approached as soon as possible.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required so that NHSBT can provide this information to TARN and ICNARC for data linkage. This cannot 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 a mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A study poster has been devised. This will be provided to the participating NHS Trusts and they will be asked to display it in relevant areas (e.g. A&E department, relatives rooms, bereavement offices, Intensive Care Units, other relevant hospital wards). The poster contained an email address and a website address.

Before the trial starts, all Air Ambulance Charities will be asked to promote their involvement in the trial as they each have a good public presence and reach. As an example of this, one Charity have already posted about the trial on their website and Facebook page. If patients refuse consent when approached, then their data will not be included. Patient records will be checked for evidence of existing dissent.

A patient or the guardian of a child who has been enrolled can request withdrawal from the study at any time by notifying a member of the team at the hospital. The research team will keep records of each participant enrolled in the trial, so will be able to confirm whether the participant was enrolled or not. The research team will notify NHSBT CTU of the withdrawal request and provide the participants pseudonymised trial ID number. NHSBT CTU will then ensure that the participant's data is not used for the research. Requests for withdrawal can also be sent directly to the SWiFT trial team. Contact details are included on the website and study posters which will be displayed within the participating hospitals.

The CAG noted that the patient notifications needed to explain clearly that patients could opt-out, as they currently only provide contact details should patients have queries. Telephone, postal and email contacts also needed to be provided.

Members noted that the Privacy Notice advises that "NHSBT have special permission in place from the Confidentiality Advisory Group…" This terminology was not correct and the CAG asked that this was revised to state that "The Confidentiality Advisory Group have recommended that support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') is given for the processing of confidential patient information…"

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 NHSBT Patient & Public Advisory Group (PPAG) have been consulted. A group of patients and the public met with the trial team in 2021. At this meeting, views on consent for emergency care trials were sought. The group also reviewed the patient information and consent documents.

A member of the NHSBT PPAG in included in the Trial Steering Committee, alongside an expert service user, who will meet every six months to review the progress of the trial.

The applicants provided a document “SWiFT Data Linkage - responses from PPI group members” with the discussion. Participants only appear to have been asked one question, which was about the acceptability of collecting NHS numbers and dates of birth of patients without consent. However, the circumstances in which patients wouldn’t be consented have been explained to the participants.

Exit strategy

The applicants advised that support was required for the duration of the trial, until the last patient recruited reaches the 90-day follow-up.

Confidential patient information, required for data linkage, will be kept separately from the pseudonymised data collected for trial purposes. It will be stored on a password-protected spreadsheet which can only be accessed by statisticians working on the project. Once all participants have been recruited into the trial and the statistician has confirmed that all linkage is complete and the datasets have been validated, the confidential patient information will be securely destroyed. At this point, the dataset held by NHSBT will be fully pseudonymised.

The applicants anticipate that the final anonymised dataset will be in place by 30 September 2024.

Confidentiality Advisory Group advice conclusion

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

Request for further information

1. Confirm that patients would be approached with information about the study when they had capacity to consent. For patients who lacked capacity, their legal representative needed to be approached as soon as possible.

2. The patient notification materials need to explain clearly that patients could opt-out. Telephone, postal and email contacts also need to be provided.

3. The sentence about the Confidentiality Advisory Group in the Privacy Notice needs to be revised to state that "The Confidentiality Advisory Group have recommended that support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') is given for the processing of confidential patient information…"

Specific conditions of support

The following sets out the specific conditions of support.

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

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

   The NHS Digital **2020/21** DSPT reviews for **NHS Blood and Transplant, ICNARC and TARN** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 01 April 2022)

5. COPI Transition Applications

a. 22/CAG/0001 - Remote Covid Assessment in Primary Care (RECAP): a learning system approach to develop an early warning score for use by primary care practitioners

Context

Purpose of application

This application by Imperial College London, for the purposes of medical research, is looking at how to improve and how to predict the severity of COVID-19 and identify the need for patient hospitalisation. This will allow the development of an early warning score (RECAP).

Data used in this CAG application relate to two sources:

1.Doctaly Assist – consisting of choices presented by a WhatsApp chatbot that represent choices for severity of symptoms in a structured way, linked to patient's NHS number and thence to outcome data on COVID-19 related hospital admission (via Hospital Episode Statistics)

2. Text data collected by GPs in the medical record from patients calling NHS111 CCAS (with confidential patient information removed) and also linked to outcome data.

These items will be built into templates on the GP electronic record so the doctor can easily be prompted to ask particular questions and enter data. Record analysis will be used to work out which aspects of the RECAP score actually predicted severity, using three outcomes: admission to hospital, admission to ITU, and death.

Support is requested to allow the disclosure of confidential patient information from free text data held in the University of Oxford ORCHID environment to Imperial College London researchers from the expiry of the COPI Notice until August 2022. This is data from CCAS only. The data will be stored for 10 years after analysis and support is also requested for this, given that anonymisation of free text cannot be 100% effective.

A recommendation for class 1 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	A defined group of patients with clinical diagnosis of COVID-19 who have a series of remote contacts as part of remote monitoring for the management of deterioration in primary care.

Data sources	1. NHS 111 Covid Clinical Assessment Service (CCAS)
Identifiers required for linkage purposes	1. None – data linkage has been completed prior to COPI Notice expiry
Identifiers required for analysis purposes	1. 312,000 rows of free text which may contain some identifiers after application of an algorithm to remove any identifiable data.
Additional information	Doctaly records originally contained the NHS number for linkage purposes, but this was conducted prior to COPI Notice expiry and the NHS number has since been removed from the analysed data.

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 to transition the study to support under Regulation 5.

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.

Scope

The CAG noted that the application is currently relying on an alternative legal basis to process confidential patient information without consent, under the 'COPI notice' and that this will continue for its duration. The group therefore considered the elements of the project that are expected to be continuing following expiry of the 'COPI notice', and which require support under regulation 5.

Prospective data collection has been conducted with consent as the legal basis.

Data collected via Doctaly contains no identifiers and was collected prior to expiry of the COPI Notice.

Identifiable data is not being collected advertently. Protection of personally identifiable data (PID) in the free text has been approached in a multi-layer fashion. On import, an open source software tool for removal of PID was applied to the data (Python Scrubadub). These tools are not 100% effective, as misspellings of names and other elements are hard to catch. Secondly, all data is held within the ORCHID secure environment and any exports required by researchers (results of analysis, figures etc) are manually checked before approval. The data are also protected by applying Natural Language Processing software to the data within the secure environment. Other than a small amount of manual verification of the results against snippets of free text, the results from the analysis are suggested coded elements (in SNOMED) and relationships between the elements. Researchers are not 'reading through' any consultations. They are not looking for PID in the analysis do not expect to retrieve any. To date, they have not.

- They do not read through entries as a whole (for this reason an audit of the % PID present has not been undertaken as this would involve looking for the PID)

- Under COPI, they have trained a Natural Language Programming routine to expand medical abbreviations, correct typos and misspellings and identify a set of clinical terms based on SNOMED. Minimal access to text strings was used to cross-check. No PID was found in this process.

- Currently they are using associations between coded elements identified in the data to construct 'knowledge graphs' - relationships between symptoms and diagnosis. It is only the Knowledge Graphs that are extracted from the secure environment, all coarse data remains in the ORCHID Secure Environment.

The original data may have contained references to carers and contact details - de-identification has been applied to these using an algorithm that removes names, addresses and telephone numbers but misspellings and mistypings' may have left some fragments. The free text is Covid-specific and contains no socially sensitive information.

Practicable alternatives

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

- **Minimising flows of identifiable information**

The applicant was asked why free text could not be converted to SNOMED codes and the actual free text deleted prior to expiry of the COPI Notice. They responded to say that creation of the SNOMED codes by processing the text is an analytical operation. The text is the data. It would be like deleting the data after running an analysis. Until the work has been and published, the researchers need access to the data.

The applicant was asked why the identifiers contained within the free text could not be manually deleted prior to expiry of the COPI Notice. There are 312,000 free text entries, it would not be feasibly to manually go through each one to identify and delete the identifiers. They cannot be searched to identify odd bits of PID, as the easy targets have already been removed. Assuming 2 ½ minutes per record to check and delete this is 7 years work.

The CAG took account of the fact that the free text collected was related to COVID-19 only and did not contain any other socially sensitive information. The CAG accepted the methodology with respect to limiting the identifiability of the data.

- **Feasibility of consent**

The applicant has justified why the data collected prospectively cannot be used to answer the research question i.e. that collected with consent, by saying:

For Doctaly Assist - The consented data contains very little in terms of oxygen saturation readings – Doctaly Assist – because it was part of a monitoring programme using pulse oximeters, contains 75% complete data on oxygen saturation, allowing us to build and validate a model with oxygen saturation.

For CCAS – the text data is not limited to the data items we collected prospectively. We are using Natural language Processing and Machine Learning to identify any additional symptoms that we might have missed that could be predictive.

The CAG accepted that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Without NHS number being provided by GP practices to Oxford, primary and secondary care data (provided by NHS Digital) cannot be linked. This has occurred prior to expiry of the COPI Notice and is outside the scope of support.

The CAG accepted this explanation.

‘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.

For retrospective data collection, the research team are in the process of amending study documents to include the fact that free text data (CCAS) will be accessed post-COPI Notice. They plan to then upload approved documents to the RECAP website (link below) which includes all study materials including patient PIS.

The research team are currently in touch with the CCAS to include the RECAP link on their website i.e., a ‘public arena’, allowing patients to be notified.

Given that all data collection has already happened, prior to expiry of the COPI Notice, the National Data Opt-Out will not apply.

The CAG agreed that the notification materials needed to be updated to explain what had happened up to the point of COPI expiry, and what would happen in the future, in terms of analysis and storage of the data.

Patient and Public Involvement

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 RECAP study shares its patient and public involvement and engagement (PPIE) with a wider study called Remote by Default. Its oversight is handled by an External Advisory Group. There is a lay chair (AAN) – a woman from a minority ethnic group – and four additional lay members, with a wide spread of ethnic backgrounds genders and ages (oldest is in her 80s). The applicant explained that they deliberately did not have a separate PPI group because they believe in democratic partnership with patients and the public. The minutes of the advisory group record that the group as a whole were extremely enthusiastic about the RECAP study and the only specific comment from patients was that they wanted it to produce results as soon as possible.

The CAG was disappointed that no project-specific PPI had been undertaken. Although not a condition of support, the CAG wish to highlight their thoughts that the free text is likely to contain some identifiers, and views from a patient group on collection and storage of the free text would have been helpful.

Exit strategy

Data will continue to be analysed until August 2022.

It is apparent that 312,000 entries of free text data via CCAS cannot be fully anonymised.

Therefore, the CAG accepted that storage of the data for 10 years after the study needed to fall under the scope of support.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. To update the notification materials to explain what had happened up to the point of COPI expiry, and what would happen in the future, in terms of analysis and storage of the data.

2. Support under Regulation 5 Health Service (Control of Patient Information) Regulations 2002 will come into effect automatically following expiry of the COPI notice.

3. The National Data Opt Out will **not** apply to processing of Confidential Patient Information under Regulation 5.

4. Favourable opinion from REC **Received 27 May 2020**

5. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The applicant must ensure that NHS Digital confirmation of 'standards met' for Imperial College London and the University of Oxford is in place once support under Regulation 5 is active.** See below for further details.

6. Minutes of the meeting held on 24 February 2022

The minutes of the meeting held on 24 February 2022 were not reviewed as an outcome is pending.

7. Any other business

No other business was raised.

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

Signed – Chair		Date
Dr Tony Calland, MBE, CAG Chair		*27/05/2022*
Ms Clare Sanderson, CAG Alternate Vice-Chair		*27/05/2022*
Signed – Confidentiality Advice Team		Date
Ms Kathleen Cassidy, Confidentiality Advisor		*27/05/2022*