Minutes of the meeting of the Confidentiality Advisory Group

22 July 2021 – held via zoom

Present:

Name	
Dr Martin Andrew	CAG member
Ms Sophie Brannan	CAG member
Dr Liliane Field	CAG member
Professor Lorna Fraser	CAG member
Mr. Myer Glickman	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Dr Murat Soncul	CAG alternative vice-chair
Dr Pauline Lyseight-jones	CAG member
Mr Dan Roulstone	CAG member
Mr Umat Sabat	CAG member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Ms Emma Marshall	HRA Confidentiality Specialist

1. Introduction, apologies and declarations of interest

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **17 June 2021** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **17 June 2021** meeting application for 2 applications. The outcome for 21/CAG/0088 is pending.

3. New applications

a. 21/CAG/0104 - Enhancing Pre-hospital Chest Pain Telephone-triage Using a Prediction Model

Context

Purpose of application

This application from the University of Manchester set out the purpose of medical research that seeks to investigate whether the use of a prediction model in telephone triage can reduce the over-triage of chest pain patients.

Chest pain is one of the main symptoms of Acute Coronary Syndrome (ACS). It is also one of the most common reasons for use of ambulance services and admission to emergency departments. ACS patients typically present with chest pain, while the majority of chest pain patients transported by ambulance and admitted to emergency departments are diagnosed with non-cardiac disease. Approximately 20% of those admitted with suspected ACS go on to be diagnosed with ACS. In this application, the applicants are aiming to create and validate a prediction model for use in the pre-hospital setting.

A retrospective, observational cohort study will be conducted to collect data from the North West Ambulance Services (NWAS) EMS dispatch system for patients who called 999 with a chief complaint of chest pain. NWAS will transfer confidential patient information to the research team at the University of Manchester via nhs.net email. The consolidated dataset will then be transferred to the Manchester University NHS Foundation Trust for linkage to data held by the Trust. The linkage and pseudonymisation process will be carried out by a research nurse within the Trust. Each patient will be given a key number, containing no identifiable information, and transferred to the University of Manchester by nhs.net email. The minimum dataset required for data linkage will be shared securely by the research team with MRI NHS Trust, in order to verify the outcomes of patients. From this audit database, a pseudonymised research data set will be extracted, this will be stored at the University of Manchester. This dataset will then be stored in the Data Safe Haven at the University of Manchester and only the assigned research team will have access to those data.

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

Confidential patient information requested

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

Cohort	5,500 patients who contacted 999 with a chief complaint of chest pain, who were transported to Manchester

	University NHS Foundation Trust by ambulance for further care.
Data sources	1. Electronic patient data held by North West Ambulance Services (NWAS) NHS Trust 2. Electronic patient data held by the University of Manchester NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID Number 4. Date of birth
Identifiers required for analysis purposes	1. 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.

Data flows

The CAG agreed that the data flows involved in the application needed to be clarified. The applicants also needed to clarify the exact datasets that would be linked to at University of Manchester NHS Foundation Trust. The CAG also asked the applicants

to clarify that two trusts only are involved: the NWAS NHS Trust and the University of Manchester NHS Foundation Trust.

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 CAG agreed that it was unclear why confidential patient information needed to be disclosed to the University of Manchester before being transferred to the University of Manchester NHS Foundation Trust. The applicants had explained that information needed to be transferred to the University of Manchester so that only data for patients who had a sufficiently complete clinical record would be transferred to the Trust. The CAG was unclear on why the staff at NWAS could not check that the minimum amount of data was included in the records for each patient, before disclosing the confidential patient information directly to the University of Manchester NHS Foundation Trust. A pseudonymised or anonymised dataset could then be released to the University of Manchester.

- Feasibility of consent

The applicants cited the size of the cohort. The study is also retrospective. and the applicants advised that it would be overly burdensome to obtain contact details and seek consent. The CAG agreed that consent was not feasible.

- Use of anonymised/pseudonymised data

Confidential patient information is needed to link patient records from NWAS to the hospital records at the University of Manchester NHS Foundation Trust. The CAG agreed that confidential patient information needed to be disclosed from NWAS to the Trust but, as noted above, were not convinced that confidential patient information needed to be disclosed to the University of Manchester.

‘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 a communication strategy will be conducted by displaying summary and detailed posters at the University of Manchester NHS Foundation Trust emergency department. Posters, which describe the aim, population, methodology, and importance of the study, will be displayed. Also, a supplementary privacy notice, which includes the study information, will be posted online using the University of Manchester website. All of these documents include email and telephone contacts in case any of the public would like to withdraw from the study or has further questions.

The CAG noted the information given. Members asked that revisions were made to the patient notification materials so that information is presented in a format suitable for lay people. The notification materials also need to be disseminated via the ambulance and hospital trusts.

Further work is needed on the dissent mechanism. The CAG noted that an email address was given for the researcher at the University of Manchester. This mechanism meant that patients could not dissent to the usage of their information before it was disclosed from NWAS or from the University of Manchester NHS Foundation Trust. A mechanism for patients to register dissent before the disclosure of their confidential patient information needs to be created.

Patient and Public Involvement and Engagement

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

The applicants have worked with the Ticker Club, a voluntary organisation supported by the British Heart Foundation, who host a PPI group including members who have received treatment for heart conditions. A formal patient group meeting was held in

November 2020. The session was run with one trained researcher. An introduction was given via a short presentation followed by open discussion. Specific advice was sought with regard to the overall concept, information governance, consent and clinical implementation.

The applicants will continue formal PPI during the project and will plan to run four PPI meetings, spaced evenly through the planned phases to provide consistent, timely input.

The three lay members of the trial steering group will oversee the research. Meetings are planned to take place every three months. This will enable lay members direct authority within the research project, feeding input from the PPI meetings directly into the heart of the project.

The CAG agreed that further patient and public involvement needed to be undertaken and reported back on. This patient and public involvement should include review of the patient notification materials.

Exit strategy

The CAG noted that pseudonymised data would be disclosed from the University of Manchester NHS Foundation Trust to the University of Manchester for linkage to the same patient clinical data from NWAS. Confidential patient information will be retained by the University of Manchester for two months after the linked data is received. Members asked that the reason for retaining confidential patient information for two months was given. The CAG noted that, should the applicant decide to follow the CAG's suggestion that confidential patient information be disclosed from NWAS to the University of Manchester NHS Foundation Trust directly and pseudonymised data only disclosed to the University of Manchester, then this question will no longer be relevant.

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. The data flows need to be revised so that confidential patient information is disclosed directly from the North West Ambulance Services (NWAS) NHS Trust to the University of Manchester NHS Foundation Trust, and a pseudonymised dataset only disclosed from the University of Manchester NHS Foundation Trust, to the University of Manchester.

2. If the above revision cannot be made to the data flow, further justification needs to be provided as to why confidential patient information needs to be disclosed to the University of Manchester.

3. The data flows involved in the application need to be clarified. The exact datasets that will be linked to at the University of Manchester NHS Foundation Trust also need to be clarified.

4. Confirm that two trusts only are involved: the NWAS NHS Trust and the University of Manchester NHS Foundation Trust.

5. Revisions need to be made to the patient notification strategy and dissent mechanism as follows:

    a. Information about the study needs to be in plain English and presented in a format suitable for lay people.

    b. The notification materials need to be disseminated via the ambulance and hospital trusts.

    c. A mechanism for patients to register dissent before the disclosure of their confidential patient information needs to be created.

6. Further patient and public involvement needs to be undertaken and reported back on. This patient and public involvement should include review of the patient notification materials.

7. The reason for retaining confidential patient information for two months needs to be given. The CAG noted that, should the applicant decide to follow the CAG's suggestion that confidential patient information be disclosed from NWAS to the University of Manchester NHS Foundation Trust directly and pseudonymised data only disclosed to the University of Manchester, then this question will no longer be relevant.

b. 21/CAG/0101 - Bystander availability and AED acceptability during out-of-hospital cardiac arrest

Context

Purpose of application

This application from the University Hospital Southampton NHS Foundation Trust set out the purpose of medical research that seeks to understand how frequently bystanders are available at out of hospital cardiac arrest (OHCA) events to perform chest compressions and collect a defibrillator, and the demographics of bystanders.

During a cardiac arrest, the heart stops pumping blood to the brain. Brain cells can only survive a few minutes without oxygen, so it is vital to restore blood flow straight away. Chest compressions go some way to moving blood temporarily around the body, but the best way of saving the patient is to restart the heart as soon as possible. Defibrillators are used to deliver an electrical shock to the heart via sticky pads on the skin. Members of the public can help to save the person by using an AED until the ambulance arrives. Modern defibrillators (AEDs) are easy for any person to use and automatically provide instructions by speaking to the user when the packaging is opened. AEDs should be used within a few minutes to provide the best chance of survival. Thousands of AEDs across the UK are available, however a second person needs to be available to fetch one while the first person does chest compressions. The applicants are seeking to determine how often a second person is available and whether they can follow the instructions of the 999 call-handler to successfully fetch an AED.

This observations study will use retrospectively collected data from previously recorded telephone calls to emergency services. Calls answered by South Central Ambulance Service (SCAS) within the study period for patients experiencing an out-of-hospital cardiac arrest (OHCA) will be reviewed in order to identify outcome data. A list of calls meeting the inclusion criteria will be compiled by SCAS data analysts and recordings will be sequentially selected from the database until the sample size is reached. The student researchers will access the call recordings via a virtual private network (VPN) connection to the SCAS computer system, so that no call recordings will be stored or

transferred outside of SCAS. Outcome data of interest will be coded directly into an Excel file. This file will not contain any items of confidential patient information and will therefore be fully anonymised before quantitative analysis takes place.

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

Confidential patient information requested

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

Cohort	Calls made to 999 and recorded by South Central Ambulance Service, where cardiac arrest was identified, between 01 August 2019 and 31 December 2019. 500 calls will be included. Most calls will not have been made by those suffering a cardiac arrest, therefore the number of patients whose details may be disclosed cannot be estimated.
Data sources	3. Telephone recordings held by South Central Ambulance Service.
Identifiers required for linkage purposes	5. Gender
Identifiers required for analysis purposes	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, although the application had a medical purpose and the reasoning driving the research was in the public interest, it was uncertain that the research questions could be answered by the current study design. Before recommending support, the CAG must be assured that the public interest and benefit of the project justify the proposed breach in the common law duty of confidentiality. Members therefore determined that the outcome needed to be deferred.

The CAG also noted that the research would be undertaken using calls made in 2019. Members asked that the applicants consider using more recent calls, as bystander readiness to intervene may have changed following the Covid-19 pandemic.

Members agreed that the primary objectives of the research, such as whether competent bystanders are present and how long it took for bystanders to get an AED, are likely to be met by the study design. However, the applicants are unlikely to meet the secondary objectives of collecting the gender and age of bystanders with sufficient accuracy, as the researchers would have to guess based on the telephone recordings. The CAG was also concerned of the risk of bias that could potentially be introduced if only age and sex are the measured characteristics. Further assurance that the required data will be consistently available would also need to be provided.

Scope

The CAG noted that the applicants were seeking support for the processing of confidential patient information for both patients and “service users” (in this application, the 999 callers and other bystanders, who are not themselves patients). Members noted

that the CAG remit is limited to the processing of confidential patient information, as defined in s251 of the NHS Act 2006. Therefore, the processing of information related to the service users is outside the CAG remit.

Practicable alternatives

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

- Feasibility of consent

The applicants explained that consent would not be feasible as it may not be possible to trace those who made the calls or the patients involved.

- Use of anonymised/pseudonymised data

An anonymised dataset will be extracted. The applicants advised that the SCAS Business Analytics team, who will ensure that all calls meet the inclusion criteria, cannot undertake the listening in and extraction of data as this would be overly burdensome to the Team.

The CAG noted that the business analysts are required to verify that a number of items of information are included in the call record in order to determine that the inclusion criteria is met. Members were unclear how the analysts could determine that the inclusion is met without listening to the calls. Therefore, sufficient justification had not been given to explain why the calls needed to be accessed by the researchers, rather than the analysts undertaking the extraction of an anonymous data set. If the applicants re-applied, further justification would need to be provided on why the researchers needed to listen to the calls, including specifying the additional information that will be collected by the researchers.

'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.

No specific strategy was described, although a link was provided to a privacy notice regarding research on the SCAS website. This notice did not contain specific information about this project. On request, the applicants supplied specific information to be included on the SCAS website. This information contained email addresses for the study team and SCAS Patient Experience Service. No telephone or postal contacts were given for patients to register dissent.

The CAG noted this information. The notification did not explain that the researchers may inadvertently access confidential patient information. Those wishing to dissent were invited to contact the research team and members observed that this was too late in the process to dissent, as confidential patient information may already have been accessed by the researchers. The applicants also needed to consider whether a lead-in time, from carrying out the notification to accessing the calls, should be included.

Members agreed that the notification needed to clearly explain the research, including the potential accessing of confidential patient information and the public interest. A clear dissent mechanism also needed to be included.

Patient and Public Involvement and Engagement

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

The applicants explained that they had tested the acceptability of use of confidential patient information without consent by seeking formal peer review of the draft protocol from two doctors. The project has also been discussed with nurses and other research staff from the SCAS research and development office.

The applicants noted that SCAS had planned to set up a patient and public involvement and engagement group. However, they have been unable to do so due to the Covid-19 pandemic and resulting pressures on the SCAS.

The CAG agreed that patient and public involvement and engagement needed to be undertaken. Members suggested that the applicants undertake patient and public involvement via the patient groups and the University of Southampton, rather than relying on engagement organised by the ambulance trust. The activity would need to explore the design of the study, the potential access of confidential patient information by the researchers, and the patient notification strategy and dissent mechanism.

Confidentiality Advisory Group advice conclusion

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

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

Further information required

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

1. Further justification on the public interest in the project and how the objectives of the study will be met needs to be provided. This needs to cover the following points:

    a. Assurance needs to be provided that the secondary objectives, the collection of the age and gender of bystanders, can be reliably met.

    b. Consider whether the public interest would be better served by using calls made during and post-pandemic.

    c. Justification needs to be provided on why the SCAS business analysts cannot undertake the listening of calls and extraction of an anonymised

dataset. This needs to include the specific, additional information that will be collected by the researchers.

2. The processing of information related to the service users is outside the CAG remit.

3. The patient notification strategy and dissent mechanism needs to be revised as follows:

    a. A clear explanation of the research needs to be provided, including the potential public interest and benefit of the research and the potential access of confidential patient information that may occur.

    b. A clear dissent mechanism needs to be included.

4. Patient and public involvement and engagement needs to be undertaken. The activity needs to explore the design of the study, the potential access of confidential patient information by the researchers, and the patient notification strategy and dissent mechanism.

c. 21/CAG/0099 – Governing parental opioid use: a relational enthnography

Context

Purpose of application

This application from University of Stirling sets out the purpose of medical research that aims to better understand the treatment and care of parents who use drugs and their families, including from the perspective of professionals and service providers.

There are 4 workstreams in this study, and CAG support is only relevant regarding workstream 3, as other activities are being undertaken with consent. In workstream 3, researchers will attend, observe and listen to professional meetings at which patients are not present and where it is not possible to know in advance who is going to be discussed. Researchers will not record any confidential patient information and will make anonymised notes concerning 'Patient or Family X' and the type of issues being discussed. There is likely to be incidental disclosure of confidential patient information during these observations, and it is for these incidental disclosures that ‘s251’ support is required.

There is a growing consensus that in order to fully understand, and respond to, parental opioid and other drug use, research must take into account the wider context, rather than simply focus on drug use in isolation. Observation of professional meetings will help understand professional decision-making and how staff discuss and manage risk, make decisions together, work together, and plan care and services together. The in-depth information and learning from these observations will inform recommendations for changes to policy and practice in the future, or may inform the development of future interventions, which in turn, may lead to better treatment and better outcomes for parents who use drugs and their families.

Applicants will undertake observations of clinical practice in 3 NHS Trusts in London, and additionally in 3 other types of service provider and the equivalents in Scotland which are out of scope for support. The observations will include staff meetings, shadowing staff, discussing policies and guidelines, and additional observations described in the protocol, via several different methods depending on how the service functions. Patients are not the focus of the staff/service observations. Observations will be undertaken by a researcher from Kings College London, who will situate themselves within participating sites for a consecutive time period of between 3-6 months either full or part time. The observations will be completed over 21 months altogether. All staff observations and staff and patient interviews, and ethnographic observations of parents and families will be undertaken with written informed consent, however it is likely that most observations of clinical practice will indirectly involve other patients (for example, in meetings). Support under the regulations is required in case of accidental disclosure of confidential patient information regarding a non-consented patient during ethnographic observations of practitioners and services. The researchers have put in a number of safeguards to protect patient confidentiality including consent where possible, not recording any confidential patient information in the written field notes, and removing themselves from the area if requested. At all times, the researchers will wear their University staff badge on a lanyard whilst on site.

A recommendation for class 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	For CAG purposes support is only given regarding patients of services, not for NHS staff or family members of patients (unless they themselves are patients of the service). The cohort is: Parents who are in treatment for opioid use who are not consented into this study, whose information may be incidentally disclosed. The applicants have estimated this to approximate 144 families, however, it is not possible to predict incidental disclosures, and this could be more or less.
Data sources	Observations carried out in 3 participating NHS Trusts: • Homerton University Hospital NHS Foundation Trust • South London and Maudsley NHS Foundation Trust • Lewisham and Greenwich NHS Trust
Identifiers required for linkage purposes	No items of confidential patient information will be collected for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be collected for analysis purposes

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, as overall this application is about improving the care given to children whose parents use drugs, which links to child development; a clear medical purpose. The Members agreed there is a strong public interest in the activity.

Scope

It is noted in part of the application that sometimes as part of workstream 3, researchers may sit in on clinical consultations, and patients will be verbally consented for this. These situations will therefore be out of scope for support, as they will be undertaken with consent as the legal basis, however the CAG considered that a patient leaflet should be developed for these situations in order to provide to the patient who verbally consents to the researcher sitting in to the clinical assessment.

The CAG also considered that if these patients refused consent for observations in this context, that they were inclined towards this opt-out also applying to the MDT observation. The applicant is to consider if they will additionally ask each of these patients about a researcher observing in MDTs, otherwise the opt-out of observations of clinical consultations should also be taken as an opt-out for the MDT and the researcher should leave the room when these individuals are discussed.

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

Staff participants will be consented, and patient interviews and ethnographic observations will also be consented. Individual patients or family members will not be the direct subjects of the observations. It is not possible to consent for the incidental disclosure of confidential patient information as it is not possible to accurately predict what the exposure might be.

Service users are often not present at meetings where they are being discussed and because of the responsive nature of treatment and care of parents who use drugs and their families, team and multidisciplinary meetings are often oriented to managing crises and it is not known in advance which families will be the subject of staff discussion. It is therefore not practicable to seek consent/assent for research purposes from the families themselves. In addition, these families are often fearful of services and difficult to engage because of child protection issues and illicit drug use, and obtaining consent may not be in their best interests as it may deter them from engaging and attending the service. This issue has been agreed in discussion with senior clinicians and service users.

The Committee agreed with the justification provided that consent was not a practicable alternative.

- Use of anonymised/pseudonymised data

Confidential patient information is not required for the purpose of the study, but researchers may be exposed to confidential patient information incidentally while undertaking observations. None will be recorded. It is not possible to undertake observations in clinical areas without the risk of incidental exposure to confidential patient information. The CAG were content 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.

Families and staff will be consented for in-depth interviews. Families will be consented for ethnography (parents/families ethnography is separate to practitioners/services

ethnography). Site managers and staff will be consented for observations as part of practitioners/services ethnography. These elements are outside the scope of support, however, the various information sheets and consent forms have been included for CAG review.

The families who may be discussed in the meetings (and therefore have the potential of having their data incidentally disclosed), will be different to those consented for the in-depth interviews, and will be different to those consented for parents/families ethnography, and there is not therefore an opportunity for consent. It is additionally impossible to predict what information will be incidentally disclosed. The applicant has therefore developed a poster to be displayed in the Trusts where practitioners/services ethnography is taking place. As a response to queries, the applicant has agreed that a picture of the researcher undertaking fieldwork could be added if CAG requested. However, they did not alter the poster to include any more detailed description of the research, as they did not want to raise anxiety for parents who use drugs and do not want to deter them from attending treatment and care services.

There is currently no opt-out option, however this is not easy to implement for incidental disclosure. Other applications of this type have an option for researcher to leave the area if requested by a patient on the poster, however, the applicant argues that for this particular cohort this approach could deter people from clinical treatment, which is supported by clinicians. It is not possible to apply the national data opt-out to incidental disclosure applications. Additionally, clinicians will know that the researchers are observing and will use their own judgement as to whether patients might object based on their knowledge of the patient. The researcher will leave the clinical area if requested.

The CAG considered the poster provided, in the context of the description of what the applicants intend to include on the poster, from page 14 of the protocol; *'A prominent 'Notice' (see enclosed) will be displayed in agency waiting rooms and other public spaces to notify clients/patients and/or the public that a researcher from the University may be present ('in attendance') and may be observing (for example, in waiting rooms). The notice will provide details on how members of the public can identify the researcher and obtain more information about the study. It will also provide reassurance about confidentiality and anonymity if anyone is observed as part of the study.'*

The Committee felt that the poster provided did not tally with the description in the protocol, which was very good. The notice provided did not provide any details on the purposes of the research, or how the researcher can be identified. The Group felt strongly that the lack of re-assurance on the poster about confidentiality and anonymity regarding observations undertaken was an opportunity missed, and actually considered that the poster would provide more assurance to patients in the waiting room if it contained more information, as the research is purely for incidental disclosures when observing MDTs, and patient information is not the object of the observations. This re-

assurance is required, because the logo on the poster does state parental opioid abuse, but nothing further is explained, so this could potentially be more concerning for patients than the actual information. They agreed it would be beneficial for the applicant to add a space on the poster for a photograph of the researcher undertaking fieldwork. The Members noted that it very clearly states University of Stirling, and the logo was University of Stirling, however, their understanding was that it would actually be researchers from Kings College London undertaking the observations, and therefore they would be wearing lanyards from Kings College London. If this is the case, the Kings College logo should be added, and the text altered to say Kings College London rather than University of Stirling. The Members felt that it should be stated on the poster that the researcher will leave the clinical area if requested. This would provide an opt-out option as far as it is possible to provide one.

The CAG noted the justifications for not providing much information on the poster, and noted that it was clinicians opinion that a more detailed poster would inhibit patients from seeking clinical care. However, the CAG could only support the lack of poster, or the lack of a more detailed poster, if there was Patient and Public involvement opinions supporting this rather than clinicians only. The CAG therefore felt that it was of vital importance that the updated poster was discussed with drug using parents as part of Patient and Public Involvement, and were of the opinion that if the patients asked agreed with the clinician view that a more detailed poster would deter them from accessing the clinical care they required, then the CAG would re-consider their position regarding the poster content.

The Committee noted that there may be patients who decline consent for the consented interviews, as part of workstream 2. It is stated in the application that these patients would be different to those potentially discussed in the MDT meetings as part of workstream 3, however, if there is any possibility of these being the same cohort, their details should be passed to the clinical teams in order to ask the researcher to leave the MDT if those patients were discussed.

Staff notification

It is noted from the protocol that a participant information sheet (PIS) has been developed for site managers and practitioners, and that the staff attending the MDTs would have received a staff PIS prior to attending an MDT where observations would be taking place. The CAG considered if a separate poster for staff should be developed for clinical areas, to explain that observations were being undertaken, to ensure that all staff were aware of the research.

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 project was co-designed with service users in Scotland and England. The applicant has created a Study Patient and Public Involvement and Engagement (PPIE) group – called the 'Learning Alliance' (LA), as part of an entire workstream undertaken. Parents with lived experience of drug treatment services who are members of the multi-stakeholder, Learning Alliance (which has 30-50 members) were consulted concerning researchers' incidental access to confidential information without consent, and were supportive of this design. They were reassured that the researchers would not record patient identifiable data they overheard and that notes would be made anonymous by researchers.

The Committee were impressed with the strong Patient and Public Involvement undertaken. However, it was noted that although there are 30-50 members of the Learning Alliance, it was not clear what proportion of these members were drug-using parents, noting the alliance has been described as 'multi stake-holder'. A description of the membership of the Learning Alliance should be provided, in order to understand how many drug using parents are involved.

Exit strategy

Ethnographic fieldwork will be undertaken over 21 months, at which timepoint support under the Regulations will no longer be required, as observations will have completed. No items of confidential patient information will be collected or recorded by the researchers, without consent. The Group were content with this exit strategy.

Link between consented interviews and clinical observations

It was noted that had the same researchers been observing the MDT discussions in workstream 3, and undertaking consented interviews as part of workstream 2 with potentially some of the same patient cohort, that links could potentially be made between these observations, indirectly, as no confidential patient information would be recorded in any case. However, Members were assured that this would not be possible, due to these elements of the study being undertaken by different researchers, as advised by the patient and public involvement undertaken.

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. A patient information leaflet should be developed for situations where verbal consent is being asked of patients (for example in a one-to-one consultation if the researcher is observing the staff member).

2. Please explain how you plan to act in situations within workstream 3 where a patient refuses an observation of a consultation (assent request) and then these same patients may be discussed in an MDT. Please confirm whether you plan to ask these patients about their wishes regarding MDT observations, and ensure the researcher leaves the room during MDT discussions of those patients if required.

3. Please provide an updated poster, including the following;
    a. More information about the reason the researcher is observing (i.e. incidental disclosure of MDT and staff interaction, NOT patient information)
    b. A space for a photograph of the researcher
    c. A contact number and email address for the researcher
    d. Provide more assurance regarding anonymity and that the researchers will not be recording any confidential patient information
    e. Add Kings College London logo (and alter wording if required)
    f. Add text to state that the researcher will leave the clinical area if requested

4. Please discuss the updated poster with drug using parents as part of Patient and Public Involvement, to establish if this would deter them from accessing the clinical care they required.

5. Please consider if there is likely to be any crossover between consented patients in the interview cohort (workstream 2), and those discussed in MDTs in workstream 3, and if so, please ensure these details are passed to the clinical team in workstream 3 in order for the researcher to leave the room during discussions of those patients.

6. Please consider if staff posters should be developed for staff areas, to ensure staff are aware that observations are taking place and advise the CAG of the decision.

7. A description of the membership of the Learning Alliance should be provided, in order to understand how many drug using parents are involved.

8. Please provide evidence that NHS Digital have reviewed all relevant DSPTs, as per standard condition of support.

4. Any other business

Juliet Tizzard, HRA Director of Policy and Partnerships, presented an time on the HRA Volunteer Group.

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

Signed – Chair	Date
Minutes signed off as accurate via correspondence by Alternate Vice Chairs Dr Murat Soncul and Ms Clare Sanderson	12/10/2021
Signed – Confidentiality Advice Team	Date
Katy Cassidy	12/10/2021