



Health Research Authority

2 Redman Place
Stratford
London
E20 1JQ

Tel: 020 7104 8100
Email: cag@hra.nhs.uk

15 September 2021

Professor Anne Whittaker
University of Stirling (seconded from NHS Lothian)
NMAHP Research Unit,
Pathfoot Building, University of Stirling
Stirling
FK9 4LA

Dear Professor Whittaker,

Application title:	Governing parental opioid use: a relational ethnography
	Short title: The Relations Study_v1.0
CAG reference:	21/CAG/0099
IRAS project ID:	279078
REC reference:	21/NS/0029

Thank you for submitting a **research** application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') to process confidential patient information without consent.

Supported applications allow the controller(s) of the relevant data sources, if they wish, to provide specified information to the applicant for the purposes of the relevant activity without being in breach of the common law duty of confidence. Support provides a lawful basis to allow the information to be processed by the relevant parties for the specified purposes without incurring a breach of the common law duty of confidence only. Applicants must ensure the activity remains fully compliant with all other relevant legislation.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether application activity should be supported, and if so, any relevant conditions. This application was considered at the CAG meeting held on 22 July 2021.

This outcome should be read in conjunction with the provisional support letter dated 04 August 2021.

Health Research Authority decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

The application, to allow researchers from Kings College London, (who are not members of the direct care team) to carry out ethnographic observations of practitioners and services who provide care for parents who use drugs, and their families, and therefore may be incidentally exposed to confidential patient information, at participating NHS Trusts in London, is conditionally supported, subject to compliance with the standard and specific conditions of support.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

The applicant has stated that the following processes are outside the scope of this application and do not require support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002:

1. Phase 1:

- Workstream 1 (PPI)

2. Phase 2:

- Ethnographic fieldwork with parents who use opioids and their families (workstream 2); - consented
- Ethnographic fieldwork with Scottish practitioners/services (workstream 3)
- A critical policy analysis to contextualise the ethnographic fieldwork (workstream 4) – no confidential patient information without consent

Phase 3: dissemination

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	<p>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).</p> <p>The cohort is: Parents who are in treatment for opioid use who are not consented into this study, whose information may be incidentally disclosed.</p> <p>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.</p>
Data sources	<p>Observations carried out in 3 participating NHS Trusts:</p> <ul style="list-style-type: none"> • 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

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

- 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).**

This has been developed and provided to the CAG, who were content with this response.

- 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.**

The applicant explained that the clinician (direct care staff member) would need to establish assent/dissent and then inform the rest of the clinical team and the researcher. However, as MDTs are only one setting where patients will be discussed, it may be difficult to control researcher exposure to patient discussions in all scenarios, including multiagency meetings where workers from other services/agencies are present and discussing families (unaware of their dissent for the researcher to be party to the discussion). While attempts to prevent this occurring will be implemented, the applicants are not able to give reassurances to patients that this would not happen. Applicants will respect patient wishes where possible, and the researcher will remove themselves from situations where it is known that patients do not want the researcher to observe. The Members were content with this response.

- 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**

An updated poster has been provided, and the applicant has stated email addresses are not permitted. The CAG were satisfied that the above points were sufficiently answered in order for support to now be recommended. However the Members felt that some of the language on this poster could be more direct, and therefore are making the following strong recommendations to the applicant;

- The CAG suggested the following comment *"However, you will not be identified in any observational notes."* Could be altered to the following *"Researchers are studying how staff make decisions, so none of your personal data will be collected during the observation"*

- The CAG suggested the following comment *"The researcher will leave the meeting if you do not feel it appropriate for us to be there."* Could be altered to the following *"Please ask the researcher to leave the meeting if you do not feel it appropriate for us to be there"*
 - Regarding "email addresses are not allowed", the Committee wondered if it was possible to have a central query email address for Kings/ SLaM.
 - It was noted that the posters have a QR code to link to the website, but the website has no statements about confidentiality – it is advised that this should be expanded on the website in order for a layered notification approach to be in place.
- 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.**

The applicant has provided feedback from six parents regarding the poster and leaflet in an online meeting on the 9th August 2021. The purpose of the poster and leaflet were explained and the documents were discussed in a shared screen. Changes were made to the poster based on parents' suggestions for wording. Parents also suggested that information should be laid out more simply (e.g. in bullet points). Participants emphasised that verbal assent should be sought from parents at the same time that the leaflet is given to them. Participants liked the idea of the QR code on the leaflet that links to the project website. It does not appear that the presence of this poster would deter them from accessing clinical care. The CAG were content with this response.

- 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.**

The applicant explained that all parents who are consented into workstream 2 (family ethnography) will be asked to give their permission for the research team to notify direct care team staff that they are taking part in the research. Parents who consent into the study will be asked to name the practitioners who they want to be notified. If parents provide consent for notification, a letter will be sent to the named practitioner/services. If there is a crossover with the service ethnography (workstream 3) - conducted by a different researcher - the researcher for workstream 2 will ask the parent if they assent/dissent to the other researcher observing practice/meetings where they are discussed (incidental disclosure). If the parent expresses dissent, this will be recorded and this information will be passed to the service ethnography researcher and the service ethnography team manager so the direct care team know about the parent's decision. This will ensure that their wishes are respected as far as possible. The research team consider that consent/dissent from the parent would need to be explicit as the service ethnography researcher will not necessarily know the personal details of the parents and families in workstream 2. This will ensure the research team maintains their duty of confidentiality to research participants, respects their wishes about notification, and avoids any potential conflicts of interest in the conduct of the study. It should be noted that some parents in this study will be self-referrals and/or referred by third sector agencies and they may not wish statutory services, including the NHS, to be informed of their involvement in the research. This population of parents and families also often attend

numerous services at the same time, or over time, so obtaining assent/dissent in respect of crossover between workstream 2 and 3 will need to be an ongoing process.

The CAG were content with this response.

- 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.**

A poster has been provided that makes clear that applicants are seeking assent from staff for the researcher to be present in any observational setting. This poster will be sent to all staff in the service via email and will be put up around the building and in offices. In addition, the researchers will make their presence known and will consistently check that staff assent to any observations. The Committee were content with this response.

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

The applicant responded that the learning alliance is made up of 6 parents who are in treatment for substance use in London and Lothian, Scotland. However the CAG noted there was no detail of what proportion of the membership they represent. The website does give more detail, and the Members were content with the information that membership of the Learning Alliance – currently numbering around 50 participants — is drawn from a wide range of stakeholder communities in both England and Scotland, including parents who have lived experience of opioid dependence, other ‘affected family members’, who include kinship carers, siblings, grandparents, and family friends, young people aged between 16 and 25, who include children of parents who use(d) drugs and other youth connected to families impacted by lived experience of opioid dependence, among other interested parties.

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

Security assurances are now in place, as evidenced by the NHS Digital DSPT tracker, and the final Trust was confirmed on 7 September 2021.

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. Support only extends to England and does not cover sites in Scotland.
2. Favourable opinion from a Research Ethics Committee. **Confirmed 30 March 2021**
3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the

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

The NHS Digital **20/21** DSPT reviews for **South London and Maudsley NHS Foundation Trust** (RV5), **Homerton University Hospital NHS Foundation Trust** (RQX) and **Lewisham and Greenwich NHS Trust** (RJ2) were confirmed as '**Standards Met**' on the NHS Digital DSPT Tracker (checked 15 September 2021).

As the above conditions have been accepted and/or met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information

Application maintenance

Annual review

Please note that this legal support is subject to submission of an annual review report, for the duration of support, to show that the minimal amount of patient information is being processed and support is still necessary, how you have met the conditions or report plans, any public benefits that have arisen and action towards meeting them. It is also your responsibility to submit this report every 12 months for the entire duration that confidential patient information is being processed without consent.

The next annual review should be provided no later than **15 September 2022** and preferably 4 weeks before this date. Reminders are not issued so please ensure this is provided annually to avoid jeopardising the status of the support. Submission of an annual review in line with this schedule remains necessary even where there has been a delay to the commencement of the supported activity, or a halt in data processing. Please ensure you review the HRA website to ensure you are completing the most up to date 'section 251' annual review form as these may change.

For an annual review to be valid, there must also be evidence that the relevant DSPT submission(s) for organisations processing confidential patient information without consent are in place and have been reviewed by NHS Digital. Please plan to contact NHS Digital in advance of the CAG annual review submission date to check they have reviewed the relevant DSPTs and have confirmed these are satisfactory.

Register of Approved Applications

All supported applications to process confidential patient information without consent are listed in the published 'Register of Approved Applications'. It is a statutory requirement for the Register to be published and it is available on the CAG section of the Health Research Authority website. It contains applicant contact details, a summary of the research and other pertinent points.

This Register is used by controllers to check whether support is in place.

Changes to the application

The application and relevant documents set out the scope of the support which is in place for the application activity and any relevant restrictions around this.

Any amendments which are made to the scope of this support, including but not limited to, purpose, data flows, data sources, items of confidential patient information and processors, require submission of a formal amendment to the application. Changes to processors will require evidence of satisfactory DSPT submission. The amendment form can be found in the Confidentiality Advisory Group pages on the Health Research Authority website.

Support for any submitted amendment would not come into effect until a positive outcome letter has been issued.

Changes to the controller

Amendments which involve a change to the named controller for the application activity require the submission of a new and signed CAG application form and supporting documentation to support the application amendment. This is necessary to ensure that the application held on file appropriately reflects the organisation taking responsibility for the manner and purpose of data processing within the application, and that the legal support in place is related to the correct legal entity.

Applicants are advised to make contact with the Confidentiality Advice Team to discuss a change in controllership for an existing application in sufficient time ahead of the transfer of project responsibility to discuss the submission process timings.

Further information and relevant forms to amend the support is available on the HRA website.

Reviewed documents

The documents reviewed at the meeting are as follows.

<i>Document</i>	<i>Version</i>	<i>Date</i>
CAG application from (signed/authorised)		28 June 2021
Covering letter on headed paper		15 June 2021
GP/consultant information sheets or letters [Consent form SITE MANAGERS_Ethnography_01.11.20_v1.0]	1.0	01 November 2020
GP/consultant information sheets or letters [PIS SITE MANAGERS & PRACTITIONERS_Ethnography_01.12.20_v1.0]	1.0	01 December 2020
Other [Data flow CAG FINAL_15.06.21_v1.0]	1.0	15 June 2021
Other [Data_Management_Plan_08.02.21_v1.0]	1.0	08 February 2021
Other [Support_letter_FINCH_clinical_lead_SLAM_25.05.21]		25 May 2021
Patient Information Materials [Notice poster SITE SERVICES_01.11.20_v1.0]	1.0	01 November 2020
REC favourable opinion letter and all correspondence [REC FO]		30 March 2021
Research protocol or project proposal [PROTOCOL_RelationsStudy_16.03.21 v2.0]	2.0	16 March 2021
Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation		16 June 2021
21CAG0099 HRA Provisional outcome letter final		04 August 2021
Response to Provisional Outcome Letter - 16-08-2021		16 August 2021
Service User Information Leaflet 16.08.2021_Version 01	01	16 August 2021
Service User Relations Study Poster_16.08.2021_Version 01	01	16 August 2021
Staff Relations Study Poster_16.08.2021_Version 01	01	16 August 2021

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item are listed below.

Dr Rachel Knowles declared a conflict of interest, however she was not attending the meeting where the application was discussed, and therefore did not participate in the development of the recommendation provided by the CAG.

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

With the Group's best wishes for the success of this project.

Yours sincerely

Caroline Watchurst
Confidentiality Advisor

On behalf of the Health Research Authority

Email: cag@hra.nhs.uk

Included: List of members who considered application
Standard conditions of support

Copy to: gram.nosres@nhs.scot

**Confidentiality Advisory Group meeting attendance
22 July 2021**

Members present:

<i>Name</i>	
Dr Martin Andrew	CAG member
Ms Sophie Brannan	CAG member
Dr Liliane Field	CAG member
Professor Lorna Fraser	CAG member
Mr Myer Glickman OBE	CAG member
Dr Pauline Lyseight-Jones	CAG member
Mr Dan Roulstone	CAG member
Mr Umar Sabat	CAG member

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

Standard conditions of support

Support to process the specified confidential patient information without consent, given by the Health Research Authority, is subject to compliance with the following standard conditions of support.

The applicant and those processing the information under the terms of the support will ensure that:

1. The specified confidential patient information is only used for the purpose(s) set out in the application.
2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.
3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant, in addition to other national guidance.
4. All staff with access to confidential patient information have contractual obligations of confidentiality, enforceable through disciplinary procedures.
5. All staff with access to confidential patient information have received appropriate ongoing training to ensure they are aware of their responsibilities and are acting in compliance with the application detail.
6. Activities must be compliant with the General Data Protection Regulation and relevant Data Protection Act 2018.
7. Audit of data processing by a designated agent is facilitated and supported.
8. The wishes of patients who have withheld or withdrawn their consent are respected.
9. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be approved via formal amendment prior to changes coming into effect.
10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.
11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken/to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.