Confidentiality Advisory Group

Minutes of the meeting of the Precedent Set Review Sub Committee of the Confidentiality Advisory Group held on *12 January 2024* via correspondence.

Present:

Name	Capacity	Items
Dr Murat Soncul	Alternate Vice Chair	2a, 2b, 2c, 2d
Dr Martin Andrew	CAG Expert Member	2a & 2c
Dr Pauline Lyseight-Jones	CAG Lay Member	2b & 2d
Ms Rose Payne	CAG Lay Member	2a & 2c
Mr Dan Roulstone	CAG Expert Member	2b & 2d

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor
Mr Dayheem Sedighi	HRA Approvals Administrator

1. DECLARATIONS OF INTEREST

There were no declarations of interest.

2. NEW PRECEDENT SET REVIEW APPLICATIONS FOR CAG CONSIDERATION

2.a	**24/CAG/0004**	**Characterising the depression pathway through primary and secondary care: an epidemiological study of patient cohort, diagnostic variation, comorbidities, and treatment management**
	Chief Investigator:	Professor Rudolf Cardinal
	Sponsor:	Cambridgeshire & Peterborough NHS Foundation Trust, CPFT
	Application type:	Research

The Group reviewed the above application in line with the CAG considerations.

Summary of application

This application from Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) set out the medical research purpose of examining risk factors for depression among all people in a geographical area (all people registered with specific primary care organisations), and to examine the course of depressive illness including treatments and treatment response, across primary and secondary care services. The objectives are to understand better how current resources are being used (including how well national guidelines about treating depression are being followed), how to optimise care to create better outcomes for those experiencing depression (including examining what predicts who gets better with certain treatments and who does not), and to be able to tailor future interventions to the groups most likely to benefit from them. The resulting sample of data would be from all patients known to the primary care organisation, allowing predictors of depression to be established, with data from their secondary mental health provider (where applicable), allowing the management of depression to be examined across primary and secondary care.

's251' support is requested to allow the disclosure of confidential patient information from Mereside Medical to Cambridgeshire & Peterborough NHS Foundation Trust, for the purposes of de-identifying the dataset using a hashing algorithm, supervised by CPFT's Research Database Manager, in order to prepare the primary care dataset for linkage, as Mereside Medical do not have the technical ability to perform this process. CPFT data will also be de-identified using the same hashing algorithm, although this does not require 's251' support as this will be performed by direct care team. The data is then linked together using the irreversibly encrypted NHS number (research pseudonym). The final analysis dataset will not contain any identifiers, except for date of death.

Confidential information requested

Cohort	All clinical records available to Mereside Medical (Staploe, Cathedral and Haddenham practices, ~44,000 patients) - People with depressive disorders, and controls (all others in the primary care data set) All clinical records available to CPFT (~750,000 patients)

Data sources	1. Primary care practice group (Mereside Medical) medical records at: a. Staploe Medical Centre b. Cathedral Medical Centre c. Haddenham Surgery 2. Cambridgeshire & Peterborough NHS Foundation Trust, CPFT, medical records
Identifiers disclosed to CPFT from Mereside Medical	1. Name 2. NHS number 3. Hospital ID 4. GP registration 5. Date of Birth 6. Date of death 7. Postcode 8. Gender 9. Ethnicity
Identifiers required for linkage purposes	Linkage will be based on the irreversibly encrypted NHS number (research pseudonym), and so does not require 's251'
Identifiers required for analysis purposes	1. Date of birth – modified to 1st of month 2. Date of death 3. LSOA 4. Gender 5. Ethnicity
Additional information	study-specific encryption hash key will be held by CPFT's Research Database Manager –this key will not contain any identifiable data.

Main issues considered, discussed and outcomes

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 section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was strongly in the public interest.

Regarding minimising the flow of confidential patient information, the CAG queried whether a split file approach could be used, rather than transferring all 44,000 records from the practices with complete identifiers, when only NHS number was required for linkage. The CAG asked the applicants to consider if a split file approach was possible, and if not, to provide justification as to why not.

(Action 2).

Another suggestion for reducing the flow of confidential patient information, was whether it was possible to extract data for a smaller control group rather than all other patients – although this would depend on the quality of coding and the technical capabilities of the practices. **(Action 3)**

The CAG noted that the data included children of all ages even though younger ones were unlikely to be diagnosed with depression. Members were unclear as to why including patients who were currently very young children was necessary. The Members could see some justification for the childhood history of current adults (as the study includes retrospective data) but cannot see why babies data is included. The CAG requested clear justification as to why babies data was required for this research. **(Action 4)**

The CAG agreed that the retention of date of death in full format did require support under common law, especially as any patients who died by suicide would have an inquest and in these cases the date of death would be in the public domain and easily re-identifiable. Therefore, the CAG queried if it was practicable to reduce the identifiability of date of death, for example modifying to month and year of death. **(Action 5)** If this is not possible, 's251' support will be required until the timepoint that full date of death is deleted. The applicant is therefore requested to clarify the timepoint full date of death will be deleted, as this is the exit strategy from 's251' support. (**Action 6**)

The CAG noted that the PPI group only consisted of three individuals who had lived experience of depression. The CAG agreed that the PPI was inadequate and needed to be expanded to be more proportionate to the size of the cohort to explicitly discuss the acceptability of the use of confidential patient information without consent for the purposes of this specific project. The CAG suggested that the applicant should be able to find a representative population via the Practice Patient Participation group. **(Action7)**.

The CAG noted that the generic statement in the privacy notice on the practice website was inadequate for the purposes of a patient notification mechanism for this application. The CAG requested a newly developed patient notification document which was specific to this project. The CAG also suggested posters for the GP practices, to be displayed at least 6-8 weeks prior to data extraction, to allow opt out, and a patient notification about this specific study for the practice websites to be developed. The CAG also requested a study specific opt-out mechanism was developed which was easily accessible, by including a phone number, email and postal address on the relevant patient notifications. The notification documents should be reviewed by a group of patients and the public for accessibility. **(Action 8.)**

<u>Confidentiality Advisory Group advice:</u> Provisionally supported

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far.

The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Security assurances for 2022/23 are outstanding for the following organisations. • Staploe Medical Centre • Cathedral Medical Centre • Haddenham Surgery Please contact NHS England at exeter.helpdesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application.	
2.	Please clarify whether it is possible to use a split file approach regarding the disclosures from the GP practices to the Trust. If this is not feasible, please justify why not.	
3.	Please clarify if it would be possible to disclose a smaller control group, rather than all other patients. If this is not feasible, please justify why not.	
4.	Provide justification as to why babies data is required for this research.	
5.	Please confirm if date of death in the dataset for analysis can be modified to less than full format to avoid requiring 's251' support for the retention of this dataset. If this is not feasible, please justify why full date of death is required for analysis.	
6.	Please confirm the timepoint that full date of death will be deleted, and by which organisation, as this will represent the exit strategy from 's251' support.	

7.	Further patient and public involvement should be carried out with proportionate representative groups, particularly around the specific issue of use of confidential patient information without consent for the purposes of this application.	
8.	Please create patient notification materials specific to this project as per advice in this letter: a. Produce a new patient notification which clearly describes the purpose and content of this research application. b. Create a study specific opt-out which is clearly separated from the National Data Opt-out, which is easily accessible, by including a phone number, email and postal address. c. All newly developed patient notification materials should be reviewed by a patient and public involvement group.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

2.b	**24/CAG/0006**	**Evaluating the effectiveness and acceptability of free door to door transport to increase the uptake of breast screening appointments in Yorkshire: A cluster randomised GP pilot trial Picture**
	Chief Investigator:	Dr Charlotte Kelly
	Sponsor:	University of Hull
	Application type:	Research

The Group reviewed the above application in line with the CAG considerations.

Summary of application

This application from University of Hull set out the medical research purpose of aiming to understand if free door to door transport can help to increase the number of women attending their breast screening appointments in Yorkshire. As a feasibility trial, the primary aim is to assess the feasibility of conducting the future definitive RCT.

Breast cancer is the most commonly diagnosed cancer in women in Yorkshire, causing more than 800 deaths per year in the region. Breast screening is one of the key tools to help diagnose breast cancer at an early stage and improve survival rates. Across Yorkshire, in the three years up to 2019/20 an average of 28.6% of invited women had not attended their appointment. Among the non-attenders, a major reason was the difficulty in travelling to the appointment. This study will assess whether offering free, bookable, door-to-door transport to and from breast cancer screening appointments could increase the number of women attending screening. Applicants will compare two groups. Women registered at GPs in group one will receive information about booking free transport alongside their breast screening invitation. Women registered at GPs in group two will receive the breast screening invitation as normal with no additional offer of transport. No 's251' support is required for sending this information as this is undertaken as part of direct care. Applicants expect that providing free transport will increase the overall screening rates, resulting in earlier breast cancer diagnosis and improved survival rates. The findings from this study will inform a larger study.

's251' support is requested to use data collected by Humber and East Riding Breast Screening Service (retained at Hull University Teaching Hospitals NHS Trust) on women invited for a breast screening appointment, in order to disclose confidential patient information to NHS England, for linkage to Hospital Episode Statistics (HES) to identify ethnicity and deprivation index. An anonymous dataset will be disclosed to University of Hull for analysis. The applicants are also undertaking other methodologies which do not require 's251' support, such as consented interviews with patients, and travel providers.

Confidential information requested

Cohort	Approximately 8000 eligible women (between ages 50-70) at eight average sized GP practices, who are due to be invited for a routine breast screening appointment by the Humber and East Riding Breast Screening Service in 2024 and early 2025.
Data sources	1. Hull University Teaching Hospitals NHS Trust - Humberside Breast Screening Service – BSS/NHS Breast Screening Programme (NHSBSP) data 2. NHS England – Hospital Episode Statistics (HES)
Identifiers required for linkage purposes	1. NHS Number 2. GP registration 3. Date of Birth 4. Attendance data 5. postcode
Identifiers required for	1. Effectively anonymous for analysis

analysis purposes	

Main issues considered, discussed and outcomes

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 section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG made requests for changes to the notification material. **(Action 2)**

<u>Confidentiality Advisory Group advice:</u> Provisionally supported

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	
2.	Please update the patient notification materials as follow and provide to CAG for review: a. Poster, section under ‘who is included’, needs to be simplified and written in language suitable for a lay reader. b. Amend reference to 'ethical approval' - it is more accurate to state that the application has been supported by the Health Research Authority (HRA) on advice from the Confidentiality Advisory Group (CAG). You will also have a Favourable Opinion from the REC regarding the application. c. Provide an explanation that sending information to NHS England is about collecting data on ethnicity and	

	deprivation and then anonymising. d. Please proofread the last paragraph on the poster with regards to study specific opt out.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

2.c	**24/CAG/0007**	**Understanding the role of interaction in facilitating access to primary care**
	Chief Investigator:	Dr Rachel Rahman
	Sponsor:	Aberystwyth University
	Application type:	Research

The Group reviewed the above application in line with the CAG considerations.

Summary of application

This application from Aberystwyth University set out the medical research purpose of aiming to gain an understanding of how access to healthcare is negotiated through receptionist patient telephone calls to GP practices in Wales. To achieve this aim, the research will analyse naturally occurring reception phone calls to primary care practices using a technique called conversation analysis. This analysis will identify how elements of talk can best facilitate better understanding, reduce ambiguity and/or perceived barriers, and facilitate access to the most appropriate services whilst maintaining patient satisfaction. The research intends to use the data as a framework for future publications and training materials as a means of improving access to healthcare and healthcare communication with GP receptionists in Wales.

's251' support is requested to allow a researcher (who is not considered direct care team) to have incidental access to confidential patient information at Oak Tree Surgery GP practice, whilst anonymising recordings of phone calls for analysis. Up to 20 hours of recorded telephone calls made to the practice by patients during peak appointment booking time (typically between the hours of 8.00am and 10.00am) will be collated by the direct care team, before sharing with the researcher. An anonymous dataset will be disclosed to Aberystwyth University for analysis.

Confidential information requested

Cohort	Any patient who telephones Oak Tree Surgery GP practice during peak appointment booking time (typically between the hours of 8.00am and 10.00am) from April 2024 (until when?)

	Up to 20 hours worth – approximately 800 or more calls (but some of these could be from the same patient).
Data sources	1. Oak Tree Surgery GP practice recorded phone calls
Identifiers required during the process of anonymisation	1. name 2. address 3. date of birth 4. Other confidential patient information that may have been disclosed during the phone call.
Identifiers required for analysis purposes	None – anonymous dataset for analysis

Main issues considered, discussed and outcomes

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 section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest, noting that access to appointments is a vital determinant of outcomes in primary care, and this is more important than ever at the moment.

Regarding patient and public involvement (PPI), the CAG noted that applicants sought consultation at the point of the initial design of the project and did not explicitly discuss the use of identifiable data without consent. The CAG agreed that the PPI was inadequate and needed to be expanded to be more proportionate to the size of the cohort to explicitly discuss the acceptability of this use of confidential patient information without consent for the purposes of this application. The CAG suggested that the applicant should be able to find a representative population via the Practice Patient Participation group. This PPI should be representative of the specific local footprint and population, rather than national or university based. **(Action 3)**

The CAG questioned if posters may be limited in reach because many people would not physically attend the surgery, although it is noted that the audio files will be extracted 1 month after the phone call is made, so there is a possibility of some individuals seeing it if they did attend in person. The CAG noted that the applicant has also contacted Oak Tree Surgery to see how feasible it would be to edit the automated message to make patients aware that the research is going on, and where they can find more information about the research and how to opt out. The CAG noted they would be content with a very brief recorded message, pointing people to the website notification, if the practice states this is feasible. The CAG also queried if it was possible for the practice to using existing methods to reach these patients such as SMS messaging to direct

them to the already created website notification with more information. **(Action 4)**. The CAG accepted that there is a danger of lengthening the conversation with the receptionist and putting extra pressure on the practice and accept that asking the receptionist to explain to the patient is not feasible.

The CAG noted that all telephone call data will be anonymised on the NHS server itself. The CAG was unclear whether the original file was deleted after deletion of identifiers from audio file. **(Action 5)**

<u>Confidentiality Advisory Group advice:</u> Provisionally supported

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	
2.	Security assurances for Oak tree surgery – under Cwm Taf Morgannwg University Health Board are required prior to 's251' support being in place. However the Confidentiality Advice Team is in communication with the Welsh IG team, and therefore the applicant does not needThe CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation: to respond to this point, this is for information only.	
3.	Further patient and public involvement should be carried out with proportionate representative groups, particularly around the specific issue of use of confidential patient information without consent.	

4.	Please confirm if it is feasible for the practice to utilise existing methods to expand the patient notification strategy, such as SMS messaging to direct patients to the website notification, or a very short addition to the recorded message.	
5.	Clarify whether the original audio file is going to be deleted after anonymisation.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

2.d	**24/CAG/0015**	**The Rituals of Integrated Working: Promoting and Improving Integrated Care**
	Chief Investigator:	Dr Jenelle Clarke
	Sponsor:	University of Kent
	Application type:	Research

The Group reviewed the above application in line with the CAG considerations.

Summary of application

This application from University of Kent set out the purpose of medical research that seeks to explore how, and to what extent, everyday interactions promote or hinder integrated working, in integrated health care, including mental health services, acute services and community health services. Interactions can include activities such as meetings, informal conversations and/or clinical group discussions.

Bringing together services is often when different agencies, such as mental health and social care, join up to coordinate care around patient needs. This is sometimes referred to as ‘joined up’ or ‘integrated care’. However, bringing together services can be very difficult. Different organisations and teams operate differently, and there can be confusion, and sometimes tension, around who will do what, who will pay for it, and who has access to certain types of information. Staff and service users/carers often try to resolve these difficulties through meetings and visits. Unresolved challenges can result in poorer patient care. This study looks at what it is like to deliver and receive joined up care. It focuses on how different groups of people come to trust each other and work collaboratively through everyday encounters. Learning from this study will help improve integrated care services.

A researcher is undertaking a number of different methodologies at 4 participating Trusts, including consented staff and patient interviews and focus groups, and further work as part of work packages 2, 3 and 4. These elements

do not require ‘s251’ support.

However as part of Work Package 1, the researcher, who is not considered direct care team, is also undertaking ethnographic observations of the interactions and relationships that enable integrated and multidisciplinary working of Health care professionals working in integrated care. These include professional interactions conducted in the course of care away from patients, for example, board rounds, ward round briefings and wrap ups, referrals and Multi-Disciplinary Team (MDT) meetings, as well as informal conversations between professionals. Support under Regulation 5 is required for this aspect of the study, as the applicants may be exposed to confidential patient information when undertaking the observations. Identifiable patient information will not be recorded. The researcher will conduct staff observations for six weeks at the research sites to understand situated practices and interaction rituals (6 months total).

Confidential information requested

Cohort	Patients over the age of 16, who are under the care of participating integrated health service teams, who are discussed during staff member interactions during routine clinical discussions and team meetings, and have not provided consent. Very approximately 30 patients per team - 120 overall. Over 6 months of observations
Data sources	Clinical meetings/observations in the following participating Trusts: • Derbyshire Healthcare NHS Foundation Trust • Kent Community Health NHS Foundation Trust • Kent and Medway NHS Social Care Partnership Trust • Lincolnshire Community Health Services NHS Trust
Identifiers required for linkage purposes	No items of confidential patient information will be recorded for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be recorded for analysis purposes

Main issues considered, discussed and outcomes

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 section 251 of the NHS Act 2006.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG were broadly content with the patient engagement and involvement (PPI) undertaken but would like to know exactly what was discussed and whether representatives were supportive of this use of identifiable data without consent. **(Action 1)**

The CAG agreed that the patient notification needs further review to make it clear and easy to understand. Particularly, the sections under “What research is going on?” and “What will type of information will observed". The CAG noted the key information to set out is that Dr. Clarke (who is not part of your direct care team) might hear identifiable information about you and your care, whilst undertaking observations of clinical interactions. No identifying information will be recorded, and patient information is not the reason for observing. **(Action 2)**

<u>Confidentiality Advisory Group advice:</u> Provisionally supported

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Please provide detailed feedback on exactly what was discussed with the PPI group, specifically whether representatives were supportive of this use of identifiable data without consent.	
2.	Please update the patient notification materials as follow and provide to CAG for review: a. Proofread and make it clear and easy to understand. b. Please ensure the breach of confidentiality is clearly described – ie. Dr. Clarke (who is not part of your direct care team) might hear identifiable information about you and your care, whilst undertaking observations of	

	clinical interactions. No identifying information will be recorded, , and patient information is not the reason for observing	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

Dr Murat Soncul	30 January 2024
…….	……..
Signed – Alternate Vice Chair	*Date*
Dayheem Sedighi	26 January 2024
…….	……..
Signed – HRA Approvals Administrator	*Date*