Confidentiality Advisory Group

Minutes of the meeting of the Precedent Set Review Sub Committee of the Confidentiality Advisory Group held on *17 November 2023* via correspondence

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Present:

Name	Capacity	Items
Dr Patrick Coyle	CAG Vice Chair	Item 2.1 & 2.2
Dr Sandra Duggan	CAG Lay Member	Item 2.1
Professor Lorna Fraser	CAG Expert Member	Item 2.2
Mr Andrew Melville	CAG Lay Member	Item 2.1
Mr Dan Roulstone	CAG Lay Member	Item 2.2

Also in attendance:

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

1. DECLARATIONS OF INTEREST

There were no declarations of interest.

2. NEW PRECEDENT SET REVIEW APPLICATIONS FOR CAG CONSIDERATION

2.1	**23/CAG/0176**	**An Anthropological Study of the Role of Music in the Diagnosis and Treatment of Psychotic Disorders**
	Chief Investigator:	Dr Iza Kavedzija
	Sponsor:	University of Cambridge

	Application type:	Research

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

Summary of application

This application from University of Cambridge set out the purpose of medical research that seeks to understand the role of music in the diagnosis and treatment of psychotic disorders.

A researcher is undertaking a number of different methodologies at Fulbourn Hospital (part of Cambridgeshire and Peterborough NHS Foundation Trust (CPFT), including consented staff observations and interviews and consented observations of group music therapy sessions. These elements do not require 's251' support.

However the researcher, who is not considered direct care team, is also undertaking ethnographic observations of Multi-Disciplinary Team (MDT) meetings of mental health 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. Observations will be recorded via handwritten field notes. Identifiable patient information will not be recorded without consent.

Confidential information requested

Cohort	Approximately 10 patients diagnosed with psychotic disorders, from two inpatient wards in Fulbourn hospital: Mulberry 1 (hyperacute ward) and 2 (chronic ward), who were discussed during the Fulbourn Hospital MDT meetings, and have not provided consent.
Data sources	1. Clinical meetings/observations in Fulbourn Hospital (part of Cambridgeshire and Peterborough NHS Foundation Trust (CPFT), recorded via written field notes.
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 Precedent Set Review Sub Committee agreed that this was a well-presented application with no issues. The Members noted that the applicant has undertaken very good patient and public involvement, as the applicant has already involved patients from a very early stage, and intends to continue to do so. The Members were pleased to see how the applicant has acted on the feedback obtained so far from patients.

Confidentiality Advisory Group advice: Fully supported

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 standard conditions of support.

2.2	**23/CAG/0177**	**Investigating potential health and health equality impacts of planning deregulation: The case of permitted development housing in England**
	Chief Investigator:	Professor Benjamin Clifford
	Sponsor:	University College London
	Application type:	Research

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

Summary of application

This application from University College London set out the purpose of medical research that seeks to use hospital admission and death records to determine the health effects of living in housing created through Permitted Development (PD) regulations, which is a category of building activity that does not require full planning permission. This research fills a vital gap in existing work to consider the health impacts and inequalities associated with PD housing in England. Poor-quality housing is linked to numerous health problems, with significant costs to health and social care systems. The Building Research Establishment estimated that the NHS spends about £2.5 billion per annum on housing and health-related conditions. Housing quality is therefore a significant public health issue. Low-quality housing disproportionately impacts lower socioeconomic groups, widening inequalities, whilst interventions which create healthy homes can help improve both health and broader social and economic outcomes. This study will inform wider policy debate about whether reduced regulation in the planning of urban spaces is aligned with the goal of creating healthier places for people to live.

To estimate the influence of PD housing on hospital admissions and deaths it is necessary to know who is living or has historically lived at a PD address and the most comprehensive way to identify these individuals is via the Personal Demographics Service (PDS). It is not possible to determine who the participants are until the point they are identified by linking an address to an entry in the PDS, which makes obtaining prior informed consent impossible. The study requires 's251 support' to allow NHS England to link between the PD housing addresses (and comparator non-PD housing addresses) that the UCL study team will provide, (which do not constitute confidential patient information), and the PDS, to identify name, NHS number, date of birth and address. These individuals are then linked to Hospital Episode Statistics (HES), Emergency Care Data Set (ECDS), and Civil registration deaths. Once linkage is complete, NHS England will pseudonymise the data to send to the UCL research team, after which, NHS England will delete the identifiable data.

Confidential information requested

Cohort	All individuals with an NHS number who have lived at an address on the PD or non-PD (comparator group) housing lists between 2010 to 2023. Based on estimates of 100,000 PD housing units - estimate sample size of approximately 230,000 people in the PD housing group. 's251' support is also required for approximately 230,000 people in the comparator group.
Data sources	1. Combined list of addresses for the study (with PD and non-PD indicator variable) created at University College London and does not constitute CPI. 2. NHS England: a. Personal Demographics Service b. Hospital Episode Statistics (HES) APC and A&E c. Emergency Care Data Set (ECDS) d. Civil registration - Deaths data
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Address (including postcode)
Identifiers required for analysis purposes	1. Gender 2. Ethnicity This will be effectively anonymous to the applicant 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.

The CAG noted that the sample size was very large (230 000 x 2) and the Members queried if all this data is needed, or if a smaller sample could give an equally valid result. The Members noted that the applicant has touched on this in the protocol, however further justification is required. **(Action 2)**

With regards to the data sources, the Sub-Committee queried why the applicant was not restricting the HES data to only the relevant diagnoses that are of interest? **(Action 3)**

With regards to A&E and ECDS data, the members were unclear on why these data sources were required, noting that these are both poorly coded for diagnoses and the applicants will have the Civil registration mortality data. The analyses section of the protocol did not provide the relevant justification. The applicant is therefore requested to provide further justification regarding the requirement for A&E and ECDS data. (**Action 4)**

The CAG noted that the Patient & Public Involvement (PPI) for the 'cases' seemed adequate, although noting this was not many individuals as compared to the number of individuals whose data would be linked. The Members therefore would like the applicant to continue ongoing engagement throughout the project. With regards to 'controls', Members agreed that PPI for 'controls' was inadequate and potentially biased towards cases anyway, as the CAG were not sure how representative community group staff are, in terms of the general public Therefore, the CAG asked that further patient and public involvement was undertaken for 'controls' with a representative groups. **(Action 5)**

The CAG noted that the text on website was currently inadequate for the purposes of a patient notification mechanism for this application. The CAG requested a layered approach was undertaken with an initial page in simpler language, which is easily accessible by the average reader, which leads on to further more detailed information if individuals wish to read it. The Members also requested that the website include information on some of the patient support organisations relevant to the research, for example, COPD, CVD, and housing charities. Finally, the CAG requested that website text should be reviewed by a PPI group for accessibility. It was accepted that the National Data Opt Out is the only potential opt out methodology for this study. **(Action 6)**

The CAG queried whether 'Section 251' support was also required for the flow back from NHS England of the pseudonymised linked data to the applicant. It was not clear from the application if a pseudo-ID is applied, as if one was

applied, it would be possible for the applicant to link the data back to the full postcode. Despite the full postcode as collated by the applicant not constituting 'Confidential Patient Information', the linked returned data, if able to be linked back to this full postcode, would be identifiable and still require 's251' support. Therefore, the CAG requested clarification as to whether 'section 251' support is required for the flow of data back to the applicant from NHS England (ie, is a pseudo ID applied and linked back to full post code, or is the flow actually anonymous?) If there is a pseudo-ID in the dataset, the exit strategy should be further described, to explain if the full postcode was removed from the dataset for analysis, and when the pseudo ID is either removed, or the key between pseudo-ID and full postcode deleted. The data flow diagram should also be updated. **(Action 7)**

The CAG were not clear with regards to how the data received would be accessed or onwardly shared. Therefore some clarity of the plans regarding onwards sharing/access and retention would be valuable**. (Action 8)**

Confidentiality Advisory Group advice: 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.	Provide clarification as to why this large sample size is required, and whether a smaller sample size can provide an equally valid result.	
3.	Please clarify why HES data will not be restricted to only relevant diagnoses?	
4.	Please provide further justification regarding the requirement for A&E and ECDS data	
5.	Further patient and public involvement should be carried out in line with advice in this letter; a. Further patient and public involvement should be undertaken with a group representative of the 'control'/non-PD housing group, prior to 's251' support.	

	b. Ongoing patient and public involvement and engagement is to be undertaken throughout the study. Please confirm plans for this.	
6.	Please update the website as follow and provide to CAG for review. a. A layered approach with an initial notification page in simpler language, which is easily accessible by the average reader. b. Include information on some of the patient support organisations relevant to the research, for example, COPD, CVD, and housing charities. c. The website should be reviewed by a PPI group for accessibility.	
7.	Please provide clarification as to whether 'section 251' support is required for the flow of data back to the applicant from NHS England (ie, is a pseudo ID applied and linked back to full post code, or is the flow actually anonymous? If there is a pseudo-ID in the dataset, the exit strategy should be further described, to explain if the full postcode was removed from the dataset for analysis, and when the pseudo ID is either removed, or the key between pseudo-ID and full postcode deleted. The data flow diagram should also be updated.	
8.	Please provide plans regarding onwards data sharing/access and retention.	

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

Dr Patrick Coyle 04 December 2023

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Signed – Vice Chair	*Date*
Dayheem Sedighi	27 November 2023
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Signed – HRA Approvals Administrator	*Date*