Confidentiality Advisory Group

Minutes of the meeting of the Precedent Set Review Sub Committee of the Confidentiality Advisory Group held on *15 September 2023* via correspondence.

Present:

Name	Capacity	Items
Dr Tony Calland MBE	CAG Chair	2.1
Mr David Evans	CAG Expert Member	2.1
Mr Andrew Melville	CAG Lay Member	2.1

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/0138**	**A qualitative investigation of a novel Parkinson's Disease Hub: an integrated multidisciplinary service for patients with Parkinson's and related disorders with rapidly declining condition or unmet palliative needs**
	Chief Investigator:	Dr Elisabeth Grey

	Controller:	University of Bristol
	Application type:	Research

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

Summary of application

This application from University of Bristol set out the purpose of medical research that aims to understand how the Parkinson's Disease (PD) Hub is experienced by people with PD, their informal carers and service providers.

Standard NHS care for people with PD has been criticised for detecting worsening condition too late. This can result in patients having to go to hospital for long stays when, had they been seen by a specialist sooner, their condition would not have become so bad as to need in-patient hospital care. A new service in North Bristol NHS Trust – the PD Hub - aims to ensure that people with PD whose condition rapidly gets worse are seen quickly by specialists and receive appropriate treatment, so that they do not need to be admitted to hospital.

A researcher is undertaking research using a number of different methodologies at Bristol PD Hub, including consented interviews and verbally consented observations of patient consultations. These elements do not require 's251' support. However the researcher, who is not considered direct care team, is also undertaking ethnographic observations of multidisciplinary team (MDT) meetings. Support under Regulation 5 is required for this aspect of the study as the applicant may be exposed to confidential patient information when undertaking the observations. Observations will be recorded via handwritten field notes or audio recorded voice notes. Identifiable patient information will not be recorded, and audio recordings will not be made of the meetings directly. The researcher will aim to make approximately 12 visits to the clinic over the course of nine months. MDT online meetings are also held online once a week. The researcher will aim to join approximately 15-18 of these meetings during the nine months.

Confidential information requested

Cohort	Patients who were discussed during multidisciplinary team (MDT) meetings of a Parkinson's disease service in North Bristol NHS Trust
Data sources	Multi-disciplinary Team (MDT) Meeting observations, recorded via written field notes, at North Bristol 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 linkage 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 the 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.

With regards to patient and public involvement (PPI), the Members felt that 3 PPI participants was not extensive. However, the Members acknowledged that the participants were involved in the Steering Group and contributed to design of the patient-facing materials. The use of confidential patient information without consent at MDT meetings had also been discussed at the Steering Group. The protocol referred to a possible focus group to discuss interpretation and dissemination as the project progressed. There was also a reference to contact with Parkinson's UK. The Members noted that they would encourage additional PPI, but were satisfied to recommend support for the application with the PPI undertaken, as the Sub-Committee felt this was proportionate to the breach of confidentiality.

With regards to patient notification, the Members noted that there were two mechanisms of dissemination for patient notification. This included an information leaflet and a poster. The Sub-Committee agreed that both poster and leaflet were adequate for the purposes of a patient notification mechanism for this application. A specific study opt out was included, however the National Data Opt-out could not be applied as it is not possible for incidental disclosures. The Sub-Committee noted that although the notification materials were sufficient to recommend support, the information leaflet does not currently refer to why ‘s251 support’ is required, and the role of the HRA and CAG are not explained. The Members therefore requested the patient notification materials to be updated to include a statement to state that ‘section 251 support’ was provided by the Health Research Authority (HRA), on advice from the Confidentiality Advisory Group (CAG). The Members also requested the poster and leaflet to explain why ‘s251’ support is required. (Condition 1)

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.	

The CAG also set out the following provisional specific conditions of support in addition to the standard conditions of support.

Number	Condition	Response from the applicant
1.	Please update the patient notification materials as follows, in line with advice in this letter, and provide to CAG for review; a. Add a statement to explain why 's251' support is required. b. Add a statement to state that 'section 251 support' was provided by the Health Research Authority (HRA), on advice from the Confidentiality Advisory Group (CAG).	

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

Dr Tony Calland MBE — 28th September 2023

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Signed – Chair *Date*

Dayheem Sedighi — 25th September 2023

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Signed – Insert job title *Date*