Confidentiality Advisory Group

Minutes of the meeting of the Precedent Set Review Sub Committee of the Confidentiality Advisory Group held on *01 September 2023* via correspondence.

Present:

Name	Capacity	Items
Dr Patrick Coyle	Expert Vice Chair	2.1, 2.2 and 2.3
Dr Rachel Knowles	Expert Member	2.1 and 2.3
Mr Andrew Melville	Lay Member	2.3
Ms Rose Payne	Lay Member	2.1 and 2.2
C. Marc Taylor	Expert Member	2.2

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

2.1	**23/CAG/0094**	**INSIGHT 2**
	Contact:	Professor Rachel Tribe
	Data controller:	King's College London and Guy's and St Thomas' NHS Foundation Trust are joint data controllers
	Application type:	Research

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

Summary of application

This application from King's College London and Guy's and St Thomas' NHS Foundation Trust set out the purpose of medical research that aims to understand how complications deviate from the normal trajectory of a healthy pregnancy. Applicants will investigate how maternal exposures and health (pre-pregnancy and during pregnancy) and alterations in the pregnancy environment can impact on in utero fetal wellbeing and subsequent maternal, infant and child health, with the eventual aim of developing prediction tools, preventative therapies and treatments that benefit both the mother and child. The study will be consented, and 's251' support is only required for the purposes of identifying patients to seek consent.

Women will be recruited through self-referral, which does not require 's251' support, and also from the general antenatal setting, specialist obstetric clinics, and potentially autoimmunity clinics. Potential participants will be identified by members of the research team from electronic medical records, routine clinics and clinic attendances at Guy's and St Thomas' NHS Foundation Trust. Potential participants will be contacted ahead of their scheduled appointment and sent a copy of the patient information sheet regarding the study to read prior to being approached in person. If participants do not wish to be approached in person, they will have the opportunity to inform the research team ahead of their appointment. This process requires 's251' support. Should patients consent, their participation will proceed on a consented basis.

Confidential information requested

Cohort	Approximately 2500 pregnant women. This will comprise women who have no underlying health problems and a healthy pregnancy outcome, or some form of pregnancy complication (or existing disease). The study will comprise of 3 cohorts: (A) general pregnancy cohort. Additionally, patients might be eligible for one or both of the following: (B) Preterm birth (PTB) risk sub-cohort with a high risk and a low risk arm; (C) Prenatal Drivers of Islet Autoimmunity (PISA) sub-cohort. 's251' support only required for those who have not self-referred
Data sources	1. Electronic medical records held at Guy's and St Thomas' NHS Foundation Trust and any additional sites that are added (Additional sites, including King's College Hospital, may be included at a later date)

Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID 4. Date of Birth 5. Postcode 6. Ethnicity 7. Contact details (phone number, email and postal address)
Identifiers required for analysis purposes	1. N/A as any identifiers for analysis included with consent as the legal basis under common law

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.

The Sub-Committee noted the data collected from the records. Researchers will retain hospital numbers, NHS numbers, ethnicity, date of birth, postcode and initials so they can ensure women are not recontacted about taking part. Women will be asked if they object to retention and then these identifiers will be deleted. The Sub-Committee were unclear why initials need to be collected or retained in addition to hospital number, DOB and NHS number for those who decline. (Action 1). For all the data retained with regards to those who decline to participate, the applicant should set a time limit for retention of their identifiers. (Action 2)

With regards to patient and public involvement (PPI), the Members felt that 3 PPI participants was low. This is potentially acceptable if the experience they represented is sufficiently rich, however no information is provided about how they were recruited. The applicant should therefore provide further information about representativeness of the cohort (Action 3). The applicant should also confirm that the specific issue regarding confidential patient information of potential subjects being seen by researchers who are not members of the care team in order identify their suitability for its study was discussed with the PPI participants (Action 4).

With regards to patient notification, the Members noted that it is currently unclear who the notification is aimed at. To make it clear who the cohort is, the patient notification should begin with wording that states directly this information is for pregnant women who attend the Trust, and that they may be contacted by phone/email about the study. Otherwise it is not possible for women to

understand why they might wish to dissent. An alternative method of contacting the team to opt out should be included. The Sub-Committee requested that the link to the National Data Opt Out (NDOO) should be removed from this notification, and merely stated that if an NDOO has been registered that this will be respected. The notification should be updated with these changes and an update provided to CAG (Action 5).

Finally, the Sub-Committee noted that additional sites, including King's College Hospital, may be included at a later date. The CAG agreed to recommend support for additional future sites without the applicant having to make an amendment, and so the future additional sites have been included in the scope currently supported.

<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.	Provide justification to why initials need to be retained in addition to hospital number, date of birth and NHS number with regards to not recontacting people who decline.	
2.	Please confirm a time limit to be set for retention of identifiers, for those who decline to participate in the research.	
3.	Please confirm how many people were involved in the described Patient and Public Involvement activities. Please give details of who they are, to indicate that they match the demographic and experience of the study cohort.	
4.	Provide confirmation that the use of confidential patient information without consent and outside the direct care team, was discussed as part of the Patient and Public Involvement activities.	

5.	Please update the patient notification materials as follows, in line with advice in this letter, and provide to CAG for review. a. The patient notification should begin with wording that states directly this information is for pregnant women who attend the Trust, and that they may be contacted by phone/email about the study. b. Additionally provide a telephone number for opt out purposes. c. The notification should remove the link to the National Data Opt-Out, only reference that it will be respected is required.	
The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.		

2.2	**23/CAG/0098**	**Loss of sight due to delay in treatment or review in UK HES**
	Contact:	Ms Rashmi Mathew
	Data controller:	Moorfields Eye Hospital NHS Foundation Trust
	Application type:	Research

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

Summary of application

This application from Moorfields Eye Hospital NHS Foundation Trust set out the purpose of medical research which aims to establish a current incidence rate, diagnosis and severity for patients suffering sight loss as a result of delay in their ophthalmic care treatment or review, over a one year surveillance programme operating via the British Opthalmological Surveillance Unit (BOSU) methodology, using the monthly reporting card amongst UK ophthalmologists.

A previous surveillance project established the frequency of sight loss due to delay in review or treatment was undertaken March 2015 - February 2016. The majority of cases were in patients with chronic eye conditions requiring long-term continuous follow-up, most notably glaucoma. Delayed follow-up appointments were the cause in most cases, indicating a lack of system capacity. In addition to pre-existing service pressures, the cessation of normal clinical practice during the coronavirus pandemic and reduced capacity in the return to normal service provision and the created backlog will have influenced the number and length of delays. Re-running the previous study will help to identify the magnitude of any changes in morbidity caused by harm due to

delays.

The BOSU methodology is established and has received support in principle from the CAG. Ophthalmologists will anonymously indicate that they have seen a new patient who has suffered sight loss as a result of delay in their ophthalmic care, through the BOSU reporting system via University of Dundee. The University of Dundee system will generate the initial questionnaire for the reporting ophthalmologist to fill in via the University of Dundee data safe haven online platform. The completion of this questionnaire will contain confidential patient information, and therefore requires 's251' support. Each case will be given a unique study number by the BOSU study centre. Hospital number, month and year of birth, gender, ethnicity, and postcode will be recorded alongside clinical data on the questionnaires. All identifies will be deleted once the follow-up is completed, postcode is converted to deprivation score, and duplicates identified.

Confidential information requested

Cohort	Approximately 168 – 264 (but actual incidence as yet unclear) patients suffering sight loss as a result of delay in their ophthalmic care treatment or review who report to a treating ophthalmologist across the 12 months reporting period, expected to be between October 2023 – September 2024
Data sources	1. Clinical records at the Trusts of BOSU reporting ophthalmologists
Identifiers required for de-duplication purposes	1. Unique BOSU study number 2. Gender 3. Age 4. Diagnosis 5. Postcode
Identifiers required for analysis purposes	1. Month and Year of birth 2. Gender 3. Postcode – converted to social deprivation score 4. Ethnicity Applicant states this will be an effectively anonymised dataset for analysis.
Additional information	1 year of baseline collection - Expected start date October 2023 – September 2024

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.

The Precedent Set Review Sub Committee agreed that this was a well-presented application.

With regards to the notification documents, the members wondered how accessible some of the font size might be to this cohort, and recommended that BOSU could consider more carefully how patients who have lost all or nearly all of their sight could engage with the information in the leaflet, probably with help from a carer or relative rather than staff in an eye clinic. However this is not information that the CAG require a response to (Recommendation 1)

The Precedent Set Review Sub Committee requested that a response to standard condition of support with regards to security assurances as set out below (Action 1) should be provided.

Confidentiality Advisory Group advice: Provisionally supported

The CAG was unable to recommend support to the Health Research Authority Care 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 are outstanding for the Health Information Centre - University of Dundee – Data safe haven. An approval letter from the Public Benefit and Privacy Panel (PBPP), where processing is taking place in Scotland, is accepted as evidence of adequate security assurance for organisations in Scotland. Please provide PBPP approval to CAG.	
Recommendation(s):		
1	The CAG recommended that the applicant considers methods of making the leaflets more accessible to patients with severe sight loss.	
The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.		

2.3	**23/CAG/0133**	**CATNAPS V1.0_Ethnography**
	Contact:	Professor Kristy Sanderson
	Data controller:	University of East Anglia
	Application type:	Research

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

Summary of application

This application from University of East Anglia set out the purpose of medical research that aims to co-produce and test a comprehensive fatigue risk management system for the NHS Ambulance sector, that meets the needs of staff and operations and is most likely to improve patient and staff safety. The primary output from the collected data is a collection of recommended actions to reduce fatigue and promote sleep health in NHS ambulance staff, collectively referred to as a fatigue risk management system (FRMS). To help meet this aim, the applicants have a number of different work packages, including undertaking observations whilst out on call with the ambulance crews and in the emergency operations centres (EOC - call centres).

The applicants have discussed with the data controllers – ie. the Ambulance Trusts, who have agreed that an application to CAG is required for individuals who are not considered part of the direct care team, to undertake observations in the described scenarios. Support under Regulation 5 is requested 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, and patients are not the focus of the observations.

Observers will accompany ambulance crews and EOC staff on a run of 4 consecutive shifts, typically 2 day and 2 overnight (or late) shifts, and including one weekend shift where possible. The study will aim to observe the same members of staff over the consecutive observation period, however this may not always be possible due to staffing or sickness etc.

Confidential information requested

Cohort	Patients whose confidential patient information was discussed during clinical observations at participating Ambulance Trusts It is difficult to estimate a number of patients, as this will be an unknown quantity until the observations have taken place. Approximate estimate of 6 patients per shift.
Data sources	1. Clinical observations in participating Ambulance Trust ambulances and operations centres, recorded via written field notes, at the following Trusts;

	a. South East Coast Ambulance Service NHS Foundation Trust b. East of England Ambulance Service NHS Trust c. South Western Ambulance Service NHS Foundation Trust Scottish Ambulance Service – (outside of CAG remit and will be covered by PBPP)
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 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.

The Precedent Set Review Sub Committee agreed that this was a well-presented application.

The Members recognised the difficulties that the applicant describes with regards to notification and opt out, and commented that thought has been given to the issue. The CAG noted that the National Data Opt Out (NDOO) is not mentioned in the application as applied, and that it is usually accepted as not practicable to apply the NDOO to incidental disclosures. However the Members noted that if ambulance staff are aware that a patient has registered the NDOO (if the data is available to them easily at the time of the callout/observation), then it should be respected (Action 3).

Members also noted that the application does not explicitly state that the researcher will not observe any patient interaction where a patient or carer objects or does not consent. Members would be grateful for the applicant to confirm this (Action 4).

The Precedent Set Review Sub Committee requested that the specific conditions of CAG support set out below (Action 1-2) should be complied with.

Confidentiality Advisory Group advice: Provisionally supported

The CAG was unable to recommend support to the Health Research Authority 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 2022/23 are outstanding for the following organisations: • South East Coast Ambulance Service NHS Foundation Trust • South Western Ambulance Service NHS Foundation Trust As per validation queries, 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 22/23 DSPT submissions due to a CAG application.	
3.	Provide confirm that if ambulance staff are aware that a patient has registered the National Data Opt-Out, it will be respected.	
4.	Please clarify that the researcher will not observe any patient interaction where a patient or carer objects or does not consent.	
The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.		

Dr Patrick Coyle, CAG Vice-Chair	14 September 2023
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Signed – Chair	*Date*
Dayheem Sedighi	12 Sep. 23
…….	……..
Signed – HRA Approvals Administrator	*Date*