Confidentiality Advisory Group

Minutes of the meeting of the Precedent Set Review Sub Committee of the Confidentiality Advisory Group held on 03 November 2023 via correspondence.

Present:

Name	Capacity	Items
Ms Clare Sanderson	Alternate Vice Chair	2a
Dr Harvey Marcovitch	Expert CAG Member	2a
Mr Anthony Kane	Lay CAG Member	2a

Also in attendance:

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

1. DECLARATIONS OF INTEREST

There were no declarations of interest.

2. NEW PRECEDENT SET REVIEW APPLICATIONS FOR CAG CONSIDERATION

2.**a**	**23/CAG/0170**	**Thermal retinal injury: discovering the risk of handheld laser devices**
	Chief Investigator:	Dr Ruth Derbyshire
	Sponsor:	Leeds Teaching Hospitals NHS Foundation Trust
	Application type:	Research

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

Summary of application

This application from the Leeds Teaching Hospitals NHS Foundation Trust set out the purpose of medical research which aims to establish the incidence of laser-related retinal injuries in the UK, the range of presenting symptoms and signs, natural history, prognosis, and complication rates, over a 13-month surveillance programme operating via the British Opthalmological Surveillance Unit (BOSU) methodology. In addition, the information generated could support changes to regulation of manufacture and sale of laser devices as well as providing an evidence base for future public health campaigns.

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, sex, and postcode will be recorded alongside clinical data on the questionnaires. Reporting will be carried out across a 13-month period, estimated as 01 Jan 2024 – 31 Jan 2025. A follow-up questionnaire will also be shared six months following initial reporting. 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 90-150 per year (therefore approximately 98 -163 over 13 months - however actual incidence as yet unclear) patients with a unilateral or bilateral retinal lesion with changes in visual function and fundal examination consistent with macular thermal injury in England and Wales, who report to a treating ophthalmologist across the 13 months reporting period, expected to be between 01 Jan 2024 – 31 Jan 2025
Data sources	1. Clinical records at the Trusts of BOSU reporting ophthalmologists
Identifiers required for de-duplication purposes & follow up	1. Unique BOSU study number 2. Sex 3. Diagnosis 4. Postcode 5. Month and Year of birth 6. Hospital number

Identifiers required for analysis purposes	1. Month and Year of birth 2. Sex 3. Postcode – converted to social deprivation score 4. Ethnicity This will be an effectively anonymised dataset for analysis.
Additional information	13 months of baseline collection - Expected 01 Jan 2024 – 31 Jan 2025 6 month follow up will be carried out.

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.

Confidentiality Advisory Group advice: Provisionally supported

However, 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.	PBPP approval is required as evidence of security assurances to CAG. Please provide once this is in place.	

Clare Sanderson 14/11/2023

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Signed – Chair *Date*

William Lyse 14/11/2023

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Signed – Approvals Administrator *Date*