Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

21 April 2023 via correspondence

Present:

Name	Role	Items
Ms Clare Sanderson	CAG Alternate Vice Chair	2a
Dr Sandra Duggan	CAG Member	2a
Mr Andrew Melville	CAG Member	2a

Also in attendance:

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

1. Expressions of interest

No conflicts of interest were declared.

2.New Precedent Set Review Applications

a. 23/CAG/0050 – APPROACH RCT

Context

Purpose of application

This application from University College London set out the purpose of medical research that seeks to compare the effectiveness of a theory-driven, app-based intervention that promotes brisk walking, in additional to usual care, in adults living with breast, prostate or colorectal cancer after 3 months.

A large body of evidence has shown that physical activity (PA) has multiple benefits for patients, following a cancer diagnosis. The Independent Cancer Taskforce has recommended that everyone diagnosed with cancer should receive (PA) advice as part of routine care. However, this is not always the case and a large proportion of patients are not meeting these guidelines. Two reasons are that health care professionals do not feel they are the correct source of advice and a lack of time and resources. The applicants have developed an intervention using a smartphone app which promotes brisk walking.

Lists of patients with breast, prostate or colorectal cancer will be provided to the researchers, who will then access patient medical records to assess their eligibility. The eligibility check will be carried out by researchers employed by the University of Leeds. Letters will then be sent to eligible patients. The letters will be signed by a member of clinical staff at the NHS trust. The letters will also contain contact details for the research team. Patients will be followed up by a telephone call if they have not responded to the invitation within one week. Patients' participation will then proceed on a consented basis.

A recommendation for class 2, 3 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients aged 16 years and over, diagnosed with breast, prostate or colorectal cancer at a participating hospital site, and who own a smartphone that can operate the app. 472 patients will be included.
Data sources	1. Electronic patient records at participating NHS trusts
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID number 4. Date of birth 5. Date of death 6. Postcode – unit level
Identifiers required for analysis purposes	Identifiers will be retained under consent.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

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. The CAG agreed that the application was in the public interest.

Pilot

The CAG noted a pilot study had been undertaken, and noted that this had not come to CAG. This is out of scope for the current CAG application, however the Members queried if the pilot study had been undertaken with patient consent.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

The applicants advised that it was not feasible to contact patients prior to screening for eligibility. A pilot study had been undertaken, in which 1677 patients were screened to recruit 90 patients, a process which took a full-time researcher 9 months to complete. It would be difficult for NHS staff to undertake the screening and consent process due to time and resources. The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

The applicants require access to confidential patient information in order to screen for eligibility and to contact patients to seek consent. The CAG agreed that the application activity could not be undertaken in any other way.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Posters and/or leaflets will be displayed in clinics to inform patients that individuals from the University of Leeds, with contractual arrangements at the hospital, will be screening medical records for eligible patients for the trial.

Depending on the preference of the individual NHS site, brief note/compliments slips may be included with information about routine clinic appointments. Social media may also be used to inform patients about the proposed study.

The participating trusts will apply the National Data Opt-Out.

The patient notification materials will include contact details should patients want to opt-out of the screening of their records. If a patient opts out, their wish will be respected and their medical records will not be accessed or viewed in any way and they will not be invited to participate.

The CAG noted that a note or compliments slip may be included with appointment letters, but the decision is up to the participating trust. Members agreed that this would likely be a more successful way of notifying patients than use of posters and requested that this method was used wherever possible. The study should also be promoted via social media.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants consulted the two study patient representatives, who had agreed that the proposed method of screening and approaching patients should go ahead.

The patient and public involvement representatives then also facilitated a wider consultation amongst their patient and public involvement networks. A summary of the plans was circulated and 21 responses were received. Of these only 1 individual specifically expressed concern about allowing researchers outside the care team to access medical records. As this respondent had left their email address, the applicants made contact to discuss this further and, and following further explanation, the patient was happy that, as long as patients were told that this would happen and were given the option to opt out, this was acceptable. Further details including the benefits perceived by the patients who responded and the important concerns that they felt needed consideration are outlined in the summary document.

Exit strategy

Patients will be contacted for consent and their participation will proceed on a consented basis.

The patient information stored for screening and inviting purposes will be kept in the database (stored exclusively on the NHS servers/premises) for the duration of the screening period (planned to be approximately 16 months), in order to ensure that patients are not screened or invited more than once. Only the most essential information will be kept for this whole period (e.g. NHS number, as the database uses this as the primary identifier), and if data can be removed earlier it will be (e.g. if a patient declines their name, address, telephone number will be deleted). Once the recruitment phase is complete/closed, all confidential information will be deleted for all patients who have not responded to contact attempts or who have not consented to participate, and only aggregated data summarising the screening outcomes will be retained.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed

Request for further information

1. Please confirm if the pilot study was undertaken with patient consent.
2. Provide confirmation that notes or compliment slip, with information about the study, will be included with clinic letters, wherever possible, in addition to the use of posters.
3. Provide confirmation that the study will be promoted via social media and provide draft text for posts.

Specific conditions of support (provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Pending**

2. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved

the ‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information. **Confirmed:**

Due to the number of participating organisations involved it is the responsibility of University College London as controller, to ensure that participating Trusts/Organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Ms Clare Sanderson, CAG Alternate Vice-Chair		*10 May 2023*
Signed – Confidentiality Advice Team		Date
Ms Katy Cassidy, HRA Confidentiality Advisor		*27 April 2023*