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

April 2020

Present:

Name	Capacity	Items
Dr Tony Calland MBE	CAG Chair	1.a, 1.b, 1.c, 1.d
Dr Rachel Knowles	CAG member	1.b, 1.c
Ms Gillian Wells	CAG member	1.c, 1.d
Dr Martin Andrew	CAG member	1.a, 1.d
Dr Liliane Field	CAG member	1.a, 1.b

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor

1. New Precedent Set Review Applications – Research

a. 20/CAG/0029 - Incidence of Chronic Recurrent Multifocal Osteomyelitis (CRMO) in the United Kingdom (UK) and Republic of Ireland (ROI)

Context

Purpose of application

This application from the University of Cambridge set out the purpose of medical research that seeks to determine the incidence of Chronic Recurrent Multifocal Osteomyelitis (CRMO) within the UK.

CRMO, also known as chronic non-bacterial osteomyelitis (CNO), is a rare auto-inflammatory condition affecting the bones. It occurs primarily in children and teenagers, although cases in adults have been reported. Its clinical presentation is characterised by bone pan and swelling, in the absence of infection or tumour. Milder cases require treatment with nonsteroidal anti-inflammatory drugs (NSAIDS) for disease control, while more serious cases more require treatment with multiple medications, including treatments that suppress the immune system. CRMO was first identified over 40 years ago, but it is now known how common it is. The applicants seek to gather information about the prevalence of CRMO.

The study will be conducted using British Paediatric Surveillance Unit (BPSU) methodology. Each month the BPSU will send an eReporting card to all consultant paediatricians across the UK and Republic of Ireland. The card will list the conditions currently being studies, including CRMO. If a clinician has seen a child affected by CRMO they tick the corresponding box on the card and return it to BPSU. BPSU then notify the applicants and provide the contact details of the reporting clinician. The applicants then contact the clinician with a confidential case report form requesting further information, including the child's demographic details, presentation, investigations and initial management. Reporting paediatricians will be contacted again 12 months later to collect follow up information on treatment received and outcome. Some patients with CRMO are referred to and managed by paediatric orthopaedic surgeons, without input from paediatricians, therefore the applicants will also run a parallel surveillance study through the British Society for Children's Orthopaedic Surgery (BSCOS), surveying all paediatric orthopaedic surgeons. The same case report and follow-up forms from the BPSU survey will be used for initial case identification and follow-up.

A recommendation for class 1,2 4, 5 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	135 patients diagnosed with CRMO
Data sources	1. Clinicians reporting cases via British Paediatric Surveillance Unit (BPSU) 2. Clinicians reporting cases via the British Society for Children's Orthopaedic Surgery (BSCOS)
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Date of death 4. Postcode – sector level 5. Ethnicity
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – sector level 4. Gender 5. Ethnicity

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 Sub-Committee agreed that the application had a medical purpose and was in the public interest, as little is known about Chronic Recurrent Multifocal Osteomyelitis.

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 seeking consent was not feasible due to the burden it would place on the clinical care team. Patients may already have been discharged or referred onto another hospital, and it would not be possible for the reporting clinician to contact the patient to seek consent. Some patients may also have died and the applicants wanted to avoid causing distress to their family. The applicants also sought to establish the prevalence of the condition and noted that complete case ascertainment was required. The Sub-Committee agreed that it was not feasible to seek consent, due to the need for complete case ascertainment, but noted that existing dissent or opt-out from research needed to be respected.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required so that duplicate records can be identified and removed, to confirm cases and ensure any clinical queries relating to the reported cases are addressed. The Group accepted that this could not be done 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 objection 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.

The applicant advised that patients' hospital records would hold whether a patient had dissented from the use of their records in audit or research. A public information leaflet would be made available on the study website. This leaflet advised patients to inform their doctor or

hospital if they did not want their records to be used and a link to information on the national data opt-out. This leaflet was provided for review.

The Sub-Committee agreed with the use of a leaflet and website notification. Members noted that the applicants had identified a Facebook group for parents of children with the condition and suggested that contact was made with this group in order to facilitate promotion of the study.

The Sub-Committee observed that some children with Chronic Recurrent Multifocal Osteomyelitis may be old enough to understand information about the study and asked that patient facing materials for older children were created and made available.

The Group advised that, if a patient had previously opted-out or dissented from the use of their data in research, then this must be respected.

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 applicant advised that they had spoken about the study to several parents of children affected by CRMO. The CRMO-UK Facebook Group had also been contacted. Four parents had volunteered to join the patient advisory group for the study and had provided feedback on the drafted questionnaires. The Patient and Public Involvement team at NIHR Cambridge BRC had also provided support during the process of recruiting for the patient advisory group and running the meetings. Regular virtual meetings will be held with the patient advisory group during the study in order to seek opinions and feedback.

The applicants had also contacted the research group in Cambridge who are responsible for the Improving Patient Health in CNO and SAPHO (ImPaHCS) study, who are recruiting patients with CRMO for genetic testing.

The Cambridge University Hospitals (CU) PPI panel, formed by volunteers from the public, had reviewed the public information leaflet. A consultant paediatric rheumatologist and paediatric orthopaedic surgeon had been recruited to the study management group, who will

meet on a monthly basis. The initial and follow-up questionnaires had also been reviewed by two general paediatricians and changes made as a result of their feedback.

The use of confidential patient information without consent had been discussed with the patient advisory group, who had not raised concerns, and with the Cambridge University Hospital Patient and Public Involvement panel. 15 of the 20 members of the panel raised no objection, while 4 did not object to consent not being sought and one made no comments on this aspect of the study. The Group was satisfied by the patient and public involvement carried out.

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.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Contact is to be made with the Facebook group for parents of children with the condition in order to facilitate promotion of the study.

2. Patient facing materials are to be produced for children old enough to understand information about the study.

3. Confirmation is be provided that, if a patient had previously opted-out or dissented from the use of their data in research, this will be respected.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

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. **Confirmed 06 March 2020.**

2. Confirmation provided from the IG Delivery Team at NHS Digital 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 – University of Cambridge has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 08 July 2019).**

b. 20/CAG/0030 - Optimal management of lymphoedema: do attitudes towards body weight and experiences of practitioners and patients affect patient engagement and guideline adherence?

Context

Purpose of application

This application from the University of Glasgow set out the purpose of medical research that seeks to develop understanding of the barriers and enablers of including body weight within the lymphoedema assessment and management plan.

Lymphoedema is a chronic, incurable condition which can seriously impact upon quality of life. It results from an impaired lymphatic system and can lead to swelling, pain, mobility problems, increased risk of infections and skin texture changes. Lymphoedema prevalence is rising in the developed world due to an ageing population and growing rates of obesity, chronic illness and cancer. Whilst there are a number of strategies which can be employed to manage lymphoedema, there is no known cure. Obesity has been identified as a risk factor and, as a result, lymphoedema management guidelines recommend that those presenting with lymphoedema who are overweight or obese are encouraged and supported to work towards achieving a healthy weight. However, no evidence has been published to ascertain whether

body weight is a considered part of the lymphoedema assessment and management process, and the barriers and supports that can affect this aspect of care from a patient or practitioners' perspective. The applicants seek to address this gap by conducting a study, where interviews and questionnaires will be completed by practitioners treating lymphoedema and through an online questionnaire and interviews with patients treated for lymphoedema within the UK.

The study is comprised of three phases, involving multiple data collection processes. Consent from patients will be sought for each phase, apart from a retrospective audit of lymphoedema records that will be conducted within two Welsh Health Boards, the Hywel Dda Health Board and Swansea Bay University Health Board. A member of the direct care team will select the records of up to 30 suitable patients at each board. The research staff will then access the confidential patient information on site in order to extract an anonymised dataset.

A recommendation for class 5 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	60 patients diagnosed with lymphoedema at Hywel Dda Health Board and Swansea Bay University Health Board
Data sources	1. Hywel Dda Health Board 2. Swansea Bay University Health Board
Identifiers required for linkage purposes	No identifiers are required for linkage purposes
Identifiers required for analysis purposes	No identifiers are required for analysis purposes

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 Sub-Committee agreed that the application had a medical purpose and a clear public interest.

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 applicant advised that consent was not being sought as this would be disproportionate to the audit activity being carried out. The Sub-Committee agreed that this was not sufficient justification for not seeking consent and asked that the applicant give a fuller explanation as to why consent could not be sought.

- **Use of anonymised/pseudonymised data**

The applicants require access to confidential patient information in order to extract an anonymised dataset. The Group considered whether members of the direct care team could undertake the extraction of the required data and agreed that this would not be feasible.

'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 objection 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.

A patient notification and dissent mechanism was not in place. The Sub-Committee agreed that a patient notification strategy needed to be created. Patients also needed to be given the opportunity to opt-out of the use of their data in this project.

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 applicant had sought guidance from Steering Group members, some of whom have a diagnosis of lymphoedema, when designing the recruitment materials. The applicant also intends to recruit a group of patients with lived experience of lymphoedema are given the opportunity to collaborate with the research team, via a focus group, to co-design the patient questionnaire.

The use of confidential patient information without consent had not been explored during patient and public involvement. The Group asked that the specific issue of access to confidential patient information by those outside of the direct care team without seeking consent from individual patients was discussed during patient and public involvement and engagement.

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.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Stronger justification for not seeking consent from patients whose data will be accessed needs to be provided.

2. A patient notification and dissent strategy needs to be created and details provided to the CAG.

3. The specific issue of access to confidential patient information by those outside of the direct care team without consent being sought by individual patients needs to be explored during patient and public involvement and engagement, and feedback from these discussions provided to the CAG.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

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. **Confirmed 29 September 2019.**

2. Confirmation provided from the IG Delivery Team at NHS Digital 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. **Confirmation from NHS Wales Informatics Service that the appropriate security assurance is in place for the two Health Board sites in Wales via the Caldicott Principles into Practice report (Pending).**

c. 20/CAG/0031 - Self-management and support programme for COPD (EDGE2)

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research that seeks to determine the feasibility of integrating hospital data with data collected by patients at home.

Chronic Obstructive Pulmonary Disease (COPD) is the name for a number of lung conditions. Individuals with COPD find breathing increasingly difficult due to the affect that the condition has on the lungs. COPD is a long-term disease without a known cure and is likely to become the third leading cause of death worldwide by 2020. Current treatments are focused on avoiding deterioration, minimising risk factors and reducing symptoms. Approximately 1 in 4 COPD patients in the NHS are re-admitted to hospital within 3 months of a previous visit. The applicants are seeking ways that digital technologies can be used by patients to monitor their condition at home and provide regular updates to their care team, so that the care team are aware if patients condition is deteriorating at home.

Potentially eligible patients attending or admitted to Oxford University Hospitals NHS Foundation Trust due to COPD exacerbation or a pulmonary infection will be identified by the clinical research team or by the clinical care team by accessing confidential patient information. If the clinical care team identify a suitable patient they will flag this with the research team who will approach the patient with verbal and written information about the study. Patients participation will then proceed on a consented basis. Patients will be given a tablet computer running the EDGE mHealth application and asked to wear the monitoring device as often as possible to monitor their physical activity levels for two weeks after being discharged from hospital.

A recommendation for class 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	200 patients, who have been admitted to hospital with a diagnosis of COPD, will be invited to take part. 15 health professionals will also be invited, but this is outside the scope of s251 support.
Data sources	1. Electronic and paper patient records held at Oxford University Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Postcode – district level
Identifiers required for analysis purposes	1. Gender 2. Age

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 Group agreed that the application had a medical purpose and a clear public interest.

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**

Patients identified as eligible will be approached for consent. If they consent, then their participation in the study will proceed on a consented basis. The Sub-Committee raised no queries about this aspect of the application.

- **Use of anonymised/pseudonymised data**

Access to confidential patient information is required in order for eligible patients to be identified and approached for consent. The Sub-Committee agreed that this design was appropriate.

'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 objection 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.

All patients admitted to the Oxford University Hospitals NHS Foundation Trust are given a Patient Information Leaflet on admission. This leaflet states that: "Information may be used for approved research projects. In most instances the information will be made anonymous so that you cannot be identified. If this is not possible, we will ask your permission or request approval from the Health Research Authority's Confidentiality Advisory Group. If you are not happy with information about you being used in research projects please speak to your clinical team."

If the team are made aware of any patient requests that their data is not to be used for research purposes, these individuals will not be approached.

The Sub-Committee reviewed this information and requested that study-specific information was created, explaining the aims of the study and how to contact the study team to dissent. This information needed to be provided to the CAG for review.

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 study design was discussed with a patient discussion group, who offered advice on the need to explain how use of the tablet may help to improve patients' self-management. Changes to the patient information sheet were also suggested.

The specialist respiratory nursing team, ward nurses and physiotherapists at the hospital had been approached for comments had were supportive. Another study, relating to hypertension, had been discussed with patient and public involvement representatives, and this had included discussion of the use of confidential patient information without consent. The Sub-Committee was satisfied by the patient and public involvement carried out.

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.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Study-specific information needs to be created, explaining the aims of the study and how to contact the study team to dissent, and provided to the CAG for review.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

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. **Confirmation of a Favourable Opinion for this amendment is pending.**

2. Confirmation provided from the IG Delivery Team at NHS Digital 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: Oxford University Hospitals NHS Foundation Trust has confirmed 'Standards Met' grade on DSPT 2018/19 (by NHS Digital email dated 17 September 2019).**

d. 20/CAG/0033 - An anthropological study of the early detection of cancer

Context

Purpose of application

This application from the University of Cambridge set out the purpose of medical research that seeks to develop understanding of the practices, perceptions and experiences of scientists, health professionals and research volunteers, who are involved in scientific and clinical research studies related to the early detection of cancer in Cambridge.

The applicant will conduct interviews with clinical scientists, health professionals and research volunteers. The interviews will take place on a consented basis and support under s251 is not required for this activity. The applicants will also observe scientific practices and meetings in academic and clinical settings, shadow research dynamics in clinical research facilities and observe research volunteers outside clinical spaces. During the observation of health professionals in clinical research meetings and multi-disciplinary team meetings, where the researchers and clinicians may discuss aspects of research volunteers' participation in relevant studies, the applicant may be exposed to confidential patient information and support is sought for these incidental disclosures.

A recommendation for class 5 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	Male and female healthy volunteers and patients diagnosed with cancer, who have finished cancer treatment but are at risk of recurrence.
Data sources	1. Confidential patient information for patients discussed during clinical research meetings and multi-disciplinary team meetings at Cambridge University Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	No identifiers will be required for linkage purposes
Identifiers required for analysis purposes	No identifiers will be retained for analysis purposes

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 Sub-Committee agreed that the application was in the public interest and had a clear medical purpose.

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**

Consent will be sought from the scientists, clinical professionals and research volunteers taking part in the study. However, during their observations of clinical research meetings and multi-disciplinary team meetings, the applicant may be exposed to confidential patient information for other patients who have not consented. The Sub-Committee agreed that seeking consent from patients whose details may be disclosed to the researcher when carrying out observations of meetings was not feasible.

- **Use of anonymised/pseudonymised data**

The applicant may be exposed to confidential patient information disclosed when observing clinical research meetings and multi-disciplinary team meetings. This information will not be recorded by the applicant. The Sub-Committee raised no queries regarding this aspect of the study.

'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 objection 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.

Patient Information Sheets had been provided, but these appeared to relate to the consented aspects of the study. Members asked that patient notification was provided by the website. The Sub-Committee also suggested that a newsletter, with information about this aspect of the study, was created and made available to those included in the other, consented, aspects of the study.

The Sub-Committee noted that a dissent mechanism was not in place, but agreed that it would be difficult for the applicants to record that patients had opted-out as no records of the patients discussed during the observed meetings would be made.

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 study design has been discussed with several members of the research community who are involved in the early detection of cancer in Cambridge, including the clinical collaborator, the clinical lead of CuRED and the project manager of the Early Detection Programme. The applicants also sought to engage with members of the public and the principal investigator met with one patient representative from the early detection steering committee. Seven responses were also received online from volunteers from the 'People in Research' who commented on the value and readability of the patient information sheets and consent forms. Nine comments on the patient-facing documents were also provided from the 'Addenbrookes Panel' and a further focus group held with the support of an NIHR PPI facilitator at Addenbrooke's Hospital.

The use of confidential patient information without consent had not been explored during patient and public involvement. The Group asked that the specific issue of access to confidential patient information by those outside of the direct care team without seeking consent from individual patients was discussed during patient and public involvement and

engagement. The Group recognised the difficulties in conducting patient and public involvement, due to the Covid-19 pandemic, and suggested that an online survey was conducted with a cohort from the original study to canvass views on the use of confidential patient information without consent.

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.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Information about the application, including the observation of clinical research meetings and multi-disciplinary team meetings, should be made available on appropriate websites.

2. A newsletter, with information about this aspect of the study, is to be created and made available to those included in the other, consented, aspects of the study.

3. The specific issue of access to confidential patient information by those outside of the direct care team without consent being sought by individual patients needs to be explored during patient and public involvement and engagement, and feedback from these discussions provided to the CAG.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

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. **Confirmed 19 February 2020.**

2. Confirmation provided from the IG Delivery Team at NHS Digital 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 – Cambridge University NHS Foundation Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 19 September 2019.**

Signed – Officers of CAG	Date
Signed – Confidentiality Advice Team	Date