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

25 September 2020

Present:

Name	Capacity	Items
Dr Murat Soncul	CAG Alternative Vice-Chair	1a, 1b, 1c, 1d
Prof Barry Evans	CAG member	1a, 1b
Dr Rachel Knowles	CAG member	1b, 1c, 1d
Mr Marc Taylor	CAG member	1a, 1c, 1d

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

1. New Precedent Set Review Applications – Research

a. 20/CAG/0120 - Incidence of Avoidant/Restrictive Food Intake Disorder (ARFID) in children and young people presenting to secondary care in the UK and Ireland

Context

Purpose of application

This application from Imperial College London sets out the purpose of medical research that aims to determine the number of new cases of children and young people with Avoidance/Restrictive Food Intake Disorder (ARFID) and associated psychiatric symptoms in the UK and Republic of Ireland over one year. The study also aims to examine referral pathways, patterns of presentation, and clinical features of ARFID, including eating behaviours, medical complications and the types of medical or psychiatric presentations it is associated with. The applicants also plan to compare rates, presentation and management of ARFID with other countries, as well as generating new research questions on prognosis, long-term outcomes and treatment of ARFID.

ARFID is an umbrella term used to describe restrictive eating patterns which result in significant health problems, including weight loss, poor growth, nutritional deficits or poor emotional wellbeing. Unlike in anorexia nervosa, restrictive eating in ARFID is not associated with concerns about body image, weight or shape. To date very little is known about this disorder and its associated behaviours and outcomes in British and Irish children and adolescents.

The limited research data on ARFID means that it was excluded from the scope of the NICE (National Institute for Health and Care Excellence) guidelines on eating disorders (NG69) and therefore from commissioning guidance for children and young people with eating disorders (2015). The exclusion of ARFID from NICE guidelines has resulted in different referral pathways and availability of care depending on where in the UK patients live. The proposed research will help in improving the help that affected children and their families receive by ensuring standardised intervention, treatment paths and care.

This national active surveillance study will be established using the British Paediatric Surveillance Unit (BPSU) and Child and Adolescent Psychiatric Surveillance system (CAPSS) research methodology. Every children's doctor in the UK, through the BPSU and CAPSS, will be asked whether they have seen a child that month with ARFID. The Imperial College ARFID research team will contact reporting clinicians to ask for service specific information, information about the case reported including clinical presentation, investigations and findings, impact of the disorder and management in the form of a questionnaire. A follow up questionnaire one year later will be conducted to understand the course of the disorder, impact and further management. The research will be taking place across England, Wales, Scotland, Northern Ireland and the Republic of Ireland, however support under the Regulations only covers England and Wales.

The research team will access questionnaire data through REDCap and store as a password protected Excel sheet. The research team will not have access to the full identifiable details (such as names, etc.) of the patients that clinicians report in the surveillance, instead, they will have access to partial identifiers such as date of birth, sex and ethnicity. Each record will have a separate unique code which the research team will assign to cases. The research team will separate the identifiable data and the clinical data and use the unique code to link the two. After the 12 month follow up questionnaire has been completed date of birth will be converted to age in months for analysis. Gender, ethnicity, and sector level postcode will be retained alongside age in months for analysis, and additionally for 10 years after the study has closed. These partial identifiers will therefore also be potentially shared with other countries outside the EEA.

A recommendation for class 1, 4 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	**Estimated sample size: 180** **Reporting Instructions** requested of all consultant paediatricians and child psychiatrists in the UK and Republic of Ireland on the BPSU and CAPSS mailing list**:** Please report any child seen in the last month who meets the case definition in the UK or the Republic of Ireland.

	However support under the Regulations is given only for those patients seen in England and Wales. **BPSU** surveillance system: children and young people aged 5-15 years **CAPSS** surveillance system: children and young people aged 5-17 years Any child or adolescent aged 5 to 17 years with persistent restriction of quantity and/or range of food intake, associated with one or both of the following: • Nutritional deficiency that requires additional clinical investigation or treatment (e.g. weight loss or poor growth, micronutrient deficiency, reliance on nutritional supplementation, anaemia) that is not fully accounted for by poverty or neglect, cultural practice or an existing medical condition or another mental disorder* • Interference with day-to-day functioning due to eating behaviour (e.g. unable to eat at school or with peers, needs to take preferred foods when out of home). Not explained by ANY of the following: • Lack of available food (e.g. from poverty, famine or neglect) • Culturally sanctioned practice (e.g. endorsed religious and cultural practice) • Other known diagnosis o e.g. Allergy to specific food group (e.g. dairy) o Gastrointestinal disorder o Constipation o Swallowing difficulties o Other eating disorder e.g. anorexia nervosa, bulimia nervosa o Other medical or psychiatric disorder that fully explains food restriction (not requiring additional clinical attention) e.g. depression, anxiety, OCD, malignancy, diabetes mellitus, inflammatory bowel disease, thyroid disease *If eating disturbance occurs in the context of another condition/disorder, then in order to meet case definition for

	ARFID, the severity of eating disturbance should exceed that routinely associated with the particular condition/disorder - and warrant additional clinical attention.
Data sources	1. Reporting clinicians
Identifiers required for de-duplication and linkage with 1 year follow-up purposes	1. Sex 2. Date of Birth 3. Ethnicity 4. Sector level postcode
Identifiers required for analysis purposes	1. Sex 2. Ethnicity 3. Sector level postcode Age – Date of Birth will be converted to age in months, after it has been used at 12 months for de-duplication. The full DOB is not required for analysis.
Additional information	Reporting clinicians will not provide names and addresses to the study team.

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 was reassured that there was sufficient public interest in the research.

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**

Individual patient consent will not be sought, to ensure accurate incidence of ARFID is calculated and for complete, and unbiased, case ascertainment of the full spectrum of ARFID to be reported. Data will also be collected retrospectively from case notes. As children may not return for further appointments with the clinician who reports the child to the study, it may not be possible for clinicians to seek consent without arranging an additional visit specifically to do this, which the applicants reason would not be appropriate. The Sub-Committee were content with this justification.

- **Use of anonymised/pseudonymised data**

Confidential patient identifiers are required to allow removal of duplicate notification and for linking baseline and follow-up questionnaires. Some partial identifiers are required for analysis, to identify and report on characteristics such as age, ethnicity and region. The applicant has clarified that it is only date of birth that will be destroyed once data collection is complete – it will be converted into age in months. Gender, ethnicity, and sector level postcode will be retained for analysis. The published report of the results from this study will not include any identifiable data. ONS guidance will be followed so if there is a need to describe small cell information this will be presented by <5. The Sub-Committee were content that the use of identifiers for the described purposes was justified.

'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.

An Information sheet has been provided for doctors and for patients/parents. This is will be displayed as downloadable links on both the BPSU and CAPSS websites, which will also both contain links to the study website, hosted on the Imperial College CAMH research group website. All BPSU and CAPSS studies are advertised on the Royal College of Paediatrics and Child Health and the Royal College of Psychiatrists websites. ARFID Awareness UK, Autistica, BEAT and SEED Eating Disorders Support will promote the study on their websites, and members of the research team will use their social media connections to promote study awareness. Professionals in key fields (e.g. eating disorders services) will be provided with copies of information sheet to print for their clinic waiting rooms e.g. through the British Eating Disorders Society.

There is not a study specific process for opting out, however if a patient has informed their Doctor that they don't want their data to be used, this will be respected. The national opt out will also be respected.

The CAG were broadly content with the patient notification and opt out mechanisms, however they were not satisfied with some of the wording on the patient/parent information sheet. The phrase *'We cannot withdraw or remove personal information from the study as this would make the research invalid*' is misleading, and the Sub-committee did not accept the explanation the applicant provided for the inclusion of this statement. The CAG requested that this line is removed from the patient/parent information sheet, and new copies are to be provided to CAG.

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.

Lay members are included on the British Paediatric Surveillance Unit (BPSU) executive committee and peer review all study proposals. It is recognised by lay representatives to the BPSU, CAPSS and collaborating patient groups that seeking consent in rare disease surveillance carries a risk of bias in case ascertainment. PPI representatives from BEAT (the UK's eating disorders charity), ARFID Awareness UK, Autistica (the UK's autism research charity) and SEED Eating Disorder Support Services have been consulted about this study proposal, including collection of identifiable data without consent, and are supportive of the study. The CAG were content with the level of PPI undertaken.

Exit Strategy

Surveillance will be undertaken for 13 months, commencing in November 2020. The planned end date for all data collection is 29 November 2022, to allow for completing 1 year follow up questionnaires. Once the study is completed, all research data will be securely archived and stored for 10 years on Imperial College London premises and password protected University PC and then destroyed (in line with the recommendations of the Medical Research Council and Imperial College London). Date of birth will not be retained for 10 years, as this will be converted to age in months after the 12 month follow up. Age in months alongside sector level postcode, ethnicity and gender will be stored for 10 years after the study has ended and potentially shared with other countries outside the EEA, in anonymised format.

Sharing Data outside of UK

It is understood that the applicant plans to use the data from this study for cross country comparisons. Data sharing with other countries to pool estimates of the frequency of occurrence, is supported on the understanding that this is limited to anonymised data only.

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 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 requests for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. The phrase *'we cannot withdraw or remove personal information from the study as this would make the research invalid'* should to be removed from the patient/parent information sheet, and an updated document is to be provided to 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. Data sharing with other countries to pool estimates of the frequency of occurrence, is supported on the understanding that this is limited to anonymised data only.

2. Favourable opinion from a Research Ethics Committee.
   Confirmed 7 October 2020

3. 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 - The NHS Digital **2018/19** DSPT review for **Imperial College London - School of Public Health Medical Trials and Research (EE133887-SPHTR)** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 October 2020). The 2019/20 DSPT is currently under review by NHS Digital.

Declarations of Interest

There were no declarations of interest.

b. 20/CAG/0121- Strengthening the Implementation and Operationalisation of 'Open Disclosure' with Women and Families After Unexpected Harm in NHS Maternity Care: DISCERN study

Context

Purpose of application

This application from King's College London sets out the purpose of medical research that aims to explore the critical factors that can improve the incidence and quality of disclosure and discussion of harm or 'Open Disclosure' (OD) in NHS maternity services, and what the actual or anticipated consequences of these improvements are likely to be for different stakeholders and in what contexts. The applicants aim to generate actionable evidence and produce tailored outputs to inform maternity providers how to strengthen OD practice and processes in NHS maternity services, to improve the quality and safety of maternity care for the benefit of women, families and clinical teams.

Open disclosure (OD) – the disclosure and discussion of harm that has happened to a patient during healthcare – has been identified as important in health services. OD is now publicly recognised as an entitlement of harmed patients and families, and research has identified multiple potential benefits. However, OD is often not routinely practiced and, when it is, it often falls short of both patient and family expectations and of professional or organisational guidelines. Research shows that the issue of Open Disclosure is often problematic in maternity care, where incidents tend to have high stakes in terms of emotional, professional, and economic costs

While the barriers to improving the incidence and quality of OD have been extensively documented, how some maternity services are managing to negotiate these barriers to improve OD policies, procedures and practices has yet to be answered. A central aspect of maternity review and investigation improvement identified by the Secretary of State is communication with families, including explanation of events of harm and assurance that lessons have been learned. There is therefore a need to understand how this difficult work can be best encouraged and supported within services.

This study is being undertaken in 3 phases. Phase 1 and 3 are outside of scope of this support. Phase 2 is in scope and applicants will undertake in-depth case studies in 3 NHS maternity services. The case studies will comprise of observations of OD work routines and effects, staff interviews, patient interviews and analysis of paperwork. The case studies will be undertaken by a series of virtual visits to staff and patients, completed over 8 months. All visits will be remote/virtual due to the Covid-19 pandemic, until or unless otherwise agreed with clinical leads, however it is possible that the applicants will occasionally be observing or meeting people face-to-face rather than virtually. All staff observations and staff and patient interviews will be undertaken where possible with written informed consent, however it is likely that most observations of individual staff will indirectly involve others (for example, in meetings, training events). Support under the regulations is required in case of accidental disclosure of confidential patient information regarding a non-consented patient during either observations or interviews with staff and consented patients. The researchers have put in a number of safeguards to protect patient confidentiality including consent where possible, avoiding meetings where patient details may be disclosed, and reminding all staff and patient participants to respect patient confidentiality during interviews and observations.

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	Support is only given regarding patients of maternity services, not for NHS staff or family members of patients. The cohort are patients treated on maternity wards who are not consented into this study, whose information may be incidentally disclosed.
Data sources	Interviews and observations carried out in 3 participating NHS Trusts: • West Sussex Trust • Guys and St Thomas NHS Foundation trust • Chelsea & Westminster Hospital NHS Foundation Trust
Identifiers required for linkage purposes	No items of confidential patient information will be collected for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be collected 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 CAG was reassured that there was sufficient public interest in the research, and the research has potential to improve patient care.

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**

Staff participants will be consented, alongside patient interviews which will also be consented. Individual patients or family members will not be the direct subjects of the non-participant observations of quality and safety improvement work. However, they may be present when a researcher is observing a member of staff and, in this situation, informed written consent will also be sought from that patient/family member before the observation research commences in their presence. It is not possible to consent for the incidental disclosure of confidential patient information as it is not possible to accurately predict what the exposure might be. The Sub-Committee were content with this justification.

- **Use of anonymised/pseudonymised data**

Confidential patient information is not required for the purpose of the study, but researchers may be exposed to confidential patient information incidentally while observing maternity units and interviewing clinical staff, and consented patients. No items of confidential patient information will be collected or recorded by the researchers, without written consent. Incidental exposure to patient data will result in destruction of audio-recordings of interview, and the researcher will remove him/herself from this site of exposure immediately. The Group accepted that it is not possible to anonymise or pseudonymise all data that could be disclosed incidentally.

'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.

Researchers will promote the study by short presentations at meetings as arranged with site Principal investigators. The study will also be promoted through social media including Twitter; a project blog www.discernstudy.org and a study update newsletter. Should a patient or family member decide that they do not wish to be indirectly observed, they will be asked to notify the clinician present or the researcher, and they will have written and verbal assurance that their decision will not affect their care or treatment in any way. It is not possible to apply the national data opt out for incidental disclosure. There is no study poster to put up in maternity wards, but most of the observations will be virtual observations of staff interactions and the CAG accepted the rationale for the non-relevance of a poster. The Sub-Committee discussed the notification methods for staff members who may be observed during the study, and were content with the notification methods, however these are out of scope for support. The CAG were content with the notification and opt out methods provided for the potential incidental disclosure of confidential patient information.

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 have had extensive PPI input into the study design, which covered the observation methods proposed. Four PPI advisors have been included on the protocol as co-applicants, representing their associations and charities (The Birth Trauma Association; SANDS - the Stillbirth and Neonatal Death Charity; and Birthrights). Some of these representatives have experienced harm in maternity care themselves. These PPI representatives form the project advisory group. In addition, the Study Steering Group includes a PPI member, who has worked in maternity care quality improvement for many years. The CAG were content with the PPI input.

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 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 provide favourable opinion from the REC when available.

Request for further information

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 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
   Pending – REC review due 28 October 2020.

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission
   Confirmed:

   The **2018/19** NHS Digital DSPT reviews for **Chelsea and Westminster Hospital NHS Foundation Trust** RQM (2019/20 not yet published), **Brighton and Sussex University and Western Sussex Hospitals Trusts** RXH (covers West Sussex trust) (2019/20 not yet published), and **Guys and St Thomas' NHS Foundation Trust** RJ1 (2019/20 submitted but not reviewed) were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 12 October 2020).

Declarations of Interest

There were no declarations of interest.

c. 20/CAG/0125 - A population based study of genetic predispositions and gene-environment interactions in colorectal cancer - SEARCH Colorectal

Context

Purpose of application

This application from the University of Cambridge set out the purpose of medical research that aims to determine the contribution of cancer predisposing genes to cancer incidence, and their possible interaction with other known risk factors. The SEARCH study obtains epidemiological information and biological material on a population-based series of colorectal cancer cases, for the purpose of investigating the role of inherited genetic variation in cancer risk and clinical outcomes.

The SEARCH study began in 1996. Participants were identified by local cancer registry, the Eastern Cancer Registration and Information Centre (ECRIC). Participants were asked to provide a blood sample, from which the research team extracted DNA for genetic analyses, to complete a comprehensive questionnaire on their lifestyle and family history of cancer and gave consent for the research team to access their medical records and to retrieve pathology material. The applicants ceased recruiting new participants to the colorectal arm of SEARCH in March 2013, due to funding. The data already collected is still used for research and the applicants are seeking support to link this data to National Cancer Registration and Analysis Service (NCRAS) data held by Public Health England in order to update the data. NCRAS will also provide regular updates on vital status from routine death notification data.

The original consent form for the application contained a clause giving consent for access to patient medical records. Due to recent developments and in accordance with guidance from the Medical Research Council and the HRA on the preparation of participant information, the participant information sheets and consent forms for arms of SEARCH where new participants are still being recruited have been updated to fully explain the access to patient records and data linkages required, including specifying that patient's electronic patient records would be accessed. The applicants have determined that it would be impracticable to recontact and consent the existing participants in the SEARCH colorectal study, and were therefore seeking support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to continue to send confidential patient information to Public Health England (PHE) Cancer Registry and receive updated sensitive clinical information from the Public Health England (PHE) Cancer Registry.

Applicants are additionally seeking support for the linkage of data from the cohort of SEARCH colorectal cancer recruits to National SARS-CoV2 testing data which is also held by PHE, to identify currently unknown predisposing factors affecting the response of cancer survivors to SARS-CoV-2, and which might influence long term morbidity and mortality.

The applicants are also seeking support to receive Electronic Health Record (EHR) data, which is also held by PHE. This was queried with the applicants to clarify the data flows. PHE are able to collect electronic health records from hospitals who have an automatic feed in to PHE. Any relevant EHR data is already included into the NCRAS data which applicants receive back from PHE, so support for EHR data is already included in the flow of NCRAS data from PHE back to the SEARCH study team. It was further clarified that this is the same arrangement for HES data, which applicants are receiving, but it is included in the NCRAS data from PHE and applicants do not receive this from NHS Digital.

A recommendation for class 4 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	4,800 Cases of primary malignant colorectal cancers diagnosed between ages 18 - 69 years, who had already consented to take part in SEARCH colorectal.
Data sources	1. Public Health England: • National Cancer Registration and Analysis Service (NCRAS) data • National SARS-CoV2 testing data
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Cancer Registration identifier

Identifiers required for analysis purposes	1. No identifiers will be retained for analysis purposes
Additional information	Potentially sensitive data items required by applicants for analysis include: • Tumour site • Tumour morphology, grade and receptor status • Tumour size Number of positive nodes • Stage Treatment data • Vital status • Cause of death • SARS-CoV-2 testing data, • Electronic Health Record (EHR) for long term morbidity and mortality In order to track participants' health over the long-term and enable investigations into the determinants of health outcomes of cancer survivors in relation to the 2019 Covid19 pandemic multiple requests for morbidity data will be required: Applicants estimate that requests for National SARS-COV testing data would be made quarterly and additional health outcomes data (through NCRAS) annually for a minimum of 5 years.

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 was reassured that there was sufficient public interest in the research to justify the level of intrusion required.

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 patients had consented to take part in SEARCH colorectal study, but the consent form used at the time of recruitment had not specified that the research team would access confidential patient information contained in digital and electronic records. Almost 38,000 patients had been included in SEARCH as a whole since 1996. The applicants advised they do not have up to date information on vital status or current address. Re-consenting would therefore be impracticable, as applicants would have to obtain confidential patient information in order to find out vital status and contact details. Additionally the cost of contacting and reconsenting the number of patients that are still alive would be substantial and the applicants do not have the resources required.

The Group accepted the rationale given for not reconsenting the cohort.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link data held in the SEARCH colorectal database with NCRAS and SARS-CoV2 testing data held by PHE. The Group accepted that this could not be undertaken in any other way.

Validity of consent

The original consent form for the SEARCH study contained a clause giving consent for access to patient medical records. The original information sheets and consent forms mention the use of pathology and medical records, but not the specific linkages proposed in this application. Therefore the CAG considered the consent already obtained was not sufficient to enable the proposed data flow, and would require support under Regulation 5.

The participant information sheets and consent forms for arms of SEARCH where new participants are still being recruited have been updated to fully explain the access to patient records and data linkages required, including specifying that patient's electronic patient records would be accessed.

'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.

Patients were initially informed of the potential use of their records in the Patient Information Sheet. All patients included in this application had already provided written informed consent, agreeing to take part in the study. The Applicant informed CAG that the SEARCH website has been updated to explain that electronic patient records will be accessed and how this will be done. Contact details for the study are included, should patients wish to withdraw their consent.

Further recruitment to SEARCH colorectal is not planned. The applicant advised that, should recruitment restart, then the patient information materials would be updated to reflect that electronic patient records would be accessed and to contain further information on how patients could dissent.

The applicant additionally provided updated information that will go on the website regarding the new covid-19 data flows. However the Members felt that the website text provided does not clearly describe the linkages, their purpose, the role of PHE, and how to opt out. A condition of support was therefore added, which the applicants will need to respond to within one month from the date of this letter. Applicants are required to provide to the CAG Sub-Committee updated information to go on the website, which makes it clear what information is being linked, why, and how patients are able to raise objections.

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 original study had been reviewed by patients from the Cambridge Breast Cancer Unit, who had also reviewed the original consent form. Regular feedback was provided from patients by telephone and email, and also when returning their questionnaires, as the questionnaires contained space for free text comments.

The applicant noted that participants had given consent for the research team to obtain confidential patient information from patient records, but that this consent did not specifically

mention access to electronic patient records. Applicants conducted a survey of 100 SEARCH participants - and received feedback that all 100 participants stated that they considered the consent provided to cover all forms of the medical record including those held electronically/centrally, and therefore expected that electronic patient records would be accessed in order to obtain information. The applicants were planning to undertake focus groups with study participants that would include discussion of access to confidential patient information without consent.

The Sub-Committee noted the information given and were content with the PPI undertaken.

Exit strategy

The applicant explained that recruitment to SEARCH began over twenty years ago, and the research will run as long as grants continue to be awarded and REC approval is still in place.

Confidential patient information will be held securely and accessible only to the immediate SEARCH recruitment team for the duration of the study. All data used in research will be anonymised.

Applicants plan to retain this information for follow up for five years in the first instance and will review by 30 September 2025.

The Group agreed that the exit strategy was appropriate.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Applicants are required to provide to the CAG Sub-Committee updated information to go on the website, which makes it clear what information is being linked, why, and how to raise objections, within one month from the date of this letter.

2. Favourable opinion from a Research Ethics Committee
   Confirmed – 18 August 2020

3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission

   Confirmed:

   The **2018/19** NHS Digital DSPT review for - **University of Cambridge (School of Clinical Medicine) (**8F331) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 12 October 2020). (DSPT 2019/20 published but not yet reviewed).

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   - All staff at **National Cancer Registration and Analytical Services (Public Health England) (X25)** that are involved in processing information under this application reference should have successfully completed local data security awareness training before processing any information under support.

Declarations of Interest

There were no declarations of interest.

d. 20/CAG/0126 - A Population-based Study of Genetic Predisposition to Cancer (SEARCH) (Oesophageal Cancer, Pancreatic Cancer, Brain tumours, Non-Hodgkins, Lymphoma, Melanoma, Kidney Cancer, Bladder cancer - SEARCH Multi

Context

Purpose of application

This application from the University of Cambridge set out the purpose of medical research that aims to determine the contribution of cancer predisposing genes to cancer incidence, and their possible interaction with other known risk factors. The SEARCH study obtains epidemiological information and biological material on a population-based series of multi cancer cases, for the purpose of investigating the role of inherited genetic variation in cancer risk and clinical outcomes.

The SEARCH study began in 1996. Participants were identified by local cancer registry, the Eastern Cancer Registration and Information Centre (ECRIC), or at participating hospitals in England or Wales which recruited patients via the Cancer Research Networks. The following cancer types were studied as part of the SEARCH Multi research: bladder, kidney, oesophagus, pancreas, brain, malignant melanoma and lymphoma. Participants were asked to provide a blood sample, from which the research team extracted DNA for genetic analyses, to complete a comprehensive questionnaire on their lifestyle and family history of cancer and gave consent for the research team to access their medical records and to retrieve pathology material. The applicants ceased recruiting new participants to the multi arm of SEARCH in March 2013, due to funding. The anonymised data already collected is still used for research and the applicants are seeking support to link this data to National Cancer Registration and Analysis Service (NCRAS) data held by Public Health England in order to update the data. NCRAS also provide regular updates on vital status from routine death notification data.

The original consent form for the application contained a clause giving consent for access to patient medical records. Due to recent developments and in accordance with guidance from the Medical Research Council and the HRA on the preparation of participant information, the participant information sheets and consent forms for arms of SEARCH where new participants are still being recruited have been updated to fully explain the access to patient records and data linkages required, including specifying that patient's electronic patient records would be accessed. The applicants have determined that it would be impracticable to recontact and consent the existing participants in the SEARCH colorectal study, and were therefore seeking support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to continue to send confidential patient information to Public Health England (PHE) Cancer Registry and receive updated sensitive clinical information from the Public Health England (PHE) Cancer Registry.

Applicants are additionally seeking support for the linkage of data from the cohort of SEARCH colorectal cancer recruits to National SARS-CoV2 testing data which is also held by PHE, to identify currently unknown predisposing factors affecting the response of cancer survivors to SARS-CoV-2, and which might influence long term morbidity and mortality.

The applicants are also seeking support to receive Electronic Health Record (EHR) data, which is also held by PHE. This was queried with the applicants to clarify the data flows. PHE are

able to collect electronic health records from hospitals who have an automatic feed in to PHE. Any relevant EHR data is already included into the NCRAS data which applicants receive back from PHE, so support for EHR data is already included in the flow of NCRAS data from PHE back to the SEARCH study team. It was further clarified that this is the same arrangement for HES data, which applicants are receiving, but it is included in the NCRAS data from PHE and applicants do not receive this from NHS Digital.

A recommendation for class 4 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	3, 800 Cases of primary malignant bladder, kidney, oesophagus, pancreas, brain cancers, malignant melanoma and lymphomas diagnosed between ages 18 - 69 years, who had already consented to take part in SEARCH Multi
Data sources	1. Public Health England: • National Cancer Registration and Analysis Service (NCRAS) data • National SARS-CoV2 testing data
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Cancer Registration identifier
Identifiers required for analysis purposes	1. No identifiers will be retained for analysis purposes
Additional information	Potentially sensitive data items required by applicants for analysis include: • Tumour site • Tumour morphology, grade and receptor status

	• Tumour size Number of positive nodes • Stage Treatment data • Vital status • Cause of death • SARS-CoV-2 testing data, • Electronic Health Record (EHR) for long term morbidity and mortality In order to track participants' health over the long-term and enable investigations into the determinants of health outcomes of cancer survivors in relation to the 2019 Covid19 pandemic multiple requests for morbidity data will be required: Applicants estimate that requests for National SARS-COV testing data would be made quarterly and additional health outcomes data (through NCRAS) annually for a minimum of 5 years.

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 was reassured that there was sufficient public interest in the research to justify the level of intrusion required.

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 patients had consented to take part in SEARCH Multi study, but the consent form used at the time of recruitment had not specified that the research team would access confidential patient information contained in digital and electronic records. Almost 38,000

patients had been included in SEARCH as a whole since 1996. The applicants advised they do not have up to date information on vital status or current address. Re-consenting would therefore be impracticable, as applicants would have to obtain confidential patient information in order to find out vital status and contact details. Additionally the cost of contacting and reconsenting the number of patients that are still alive would be substantial and the applicants do not have the resources required.

The Group accepted the rationale given for not reconsenting the cohort.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link data held in the SEARCH Multi database with NCRAS and SARS-CoV2 testing data held by PHE. The Group accepted that this could not be undertaken in any other way.

Validity of consent

The original consent form for the SEARCH study contained a clause giving consent for access to patient medical records. The original information sheets and consent forms mention the use of pathology and medical records, but not the specific linkages proposed in this application. Therefore the CAG considered the consent already obtained was not sufficient to enable the proposed data flow, and would require support under Regulation 5.

The participant information sheets and consent forms for arms of SEARCH where new participants are still being recruited have been updated to fully explain the access to patient records and data linkages required, including specifying that patient's electronic patient records would be accessed.

'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.

Patients were initially informed of the potential use of their records in the Patient Information Sheet. All patients included in this application had already provided written informed consent, agreeing to take part in the study. The Applicant informed CAG that the SEARCH website has been updated to explain that electronic patient records will be accessed and how this will be done. Contact details for the study are included, should patients wish to withdraw their consent.

Further recruitment to SEARCH Multi is not planned. The applicant advised that, should recruitment restart, then the patient information materials would be updated to reflect that electronic patient records would be accessed and to contain further information on how patients could dissent.

The applicant additionally provided updated information that will go on the website regarding the new covid-19 data flows, however the Members felt that the website text provided does not clearly describe the linkages, their purpose, the role of PHE, and how to opt out. A condition of support was therefore added, which the applicants will need to respond to within one month from the date of this letter. Applicants are required to provide to the CAG Sub-Committee updated information to go on the website, which makes it clear what information is being linked, why, and how patients are able to raise objections.

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 original study had been reviewed by patients from the Cambridge Breast Cancer Unit, who had also reviewed the original consent form. Regular feedback was provided from patients by telephone and email, and also when returning their questionnaires, as the questionnaires contained space for free text comments.

The applicant noted that participants had given consent for the research team to obtain confidential patient information from patient records, but that this consent did not specifically mention access to electronic patient records. Applicants conducted a survey of 100 SEARCH participants - and received feedback that all 100 participants stated that they considered the consent provided to cover all forms of the medical record including those held electronically/centrally, and therefore expected that electronic patient records would be accessed in order to obtain information. The applicants were planning to undertake focus groups

with study participants that would include discussion of access to confidential patient information without consent.

The Sub-Committee noted the information given and were content with the PPI undertaken.

Exit strategy

The applicant explained that recruitment to SEARCH began over twenty years ago, and the research will run as long as grants continue to be awarded and REC approval is still in place.

Confidential patient information will be held securely and accessible only to the immediate SEARCH recruitment team for the duration of the study. All data used in research will be anonymised.

Applicants plan to retain this information for follow up for five years in the first instance and will review by 30 September 2025.

The Group agreed that the exit strategy was appropriate.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Applicants are required to provide to the CAG Sub-Committee updated information to go on the website, which makes it clear what information is being linked, why, and how to raise objections, within one month from the date of this letter.

2. Favourable opinion from a Research Ethics Committee
   Confirmed – 18 August 2020

3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission

   Confirmed:

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   - All staff at **National Cancer Registration and Analytical Services (Public Health England) (X25)** that are involved in processing information under this application reference should have successfully completed local data security awareness training before processing any information under support.

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