Minutes of the meeting of the Confidentiality Advisory Group

03 June 2021 – held via zoom

Present:

Name	
Dr Patrick Coyle	CAG vice-chair
Professor Barry Evans	CAG member
Dr Liliane Field	CAG member
Dr Rachel Knowles	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Pauline Lyseight-jones	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Professor Sara Randall	CAG member
Mr Dan Roulstone	CAG member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Caroline Watchurst	HRA Confidentiality Advisor

Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

1. Introduction, apologies and declarations of interest

Dr Malcolm Booth and Dr Simon Kolstoe gave apologies.

2. Support decisions

Secretary of State for Health & Social Care Decisions

No non-research applications were considered at the **06 May 2021** meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **06 May 2021** meeting applications.

3. Consideration Items

a. ECC 1-03(d)/2012 – Amendment to the National Bowel Cancer Audit

Amendment request

The NHS Digital and Clinical Effectiveness Unit (CEU) at The Royal College of Surgeons (RCS) has been commissioned to undertake work as part of the National Bowel Cancer Audit (NBOCA) programme, which is one of the Health Quality Improvement Partnership (HQIP) commissioned national clinical audits.

The amendment specified that the National Disease Registration Service, which is part of Public Health England (PHE), now collects data relating to histological and genomic tests performed within the NHS. The National Disease Registration Service already have a dataset including sporadic mutation test results (e.g. RAS and BRAF mutations), germline mutation testing (e.g. DPYD testing) and MMR IHC data. MMR and germline data are felt to be complete. The proportion of patients with somatic mutation data is lower due to

upload of results from GLHs but it is expected that this should improve over the next 12 months.

Individualised treatment based on the assessment of germline polymorphisms or sporadic abnormalities e.g. mutations occurring in tumour cells, have been key to advances in cancer medicine over the past 20 years. NICE approved indications for molecular testing in colorectal cancer now includes guidance to test for various abnormalities as described above.

Collecting genomic data derived directly from PHE will be more complete and accurate than that data derived from hospital trusts or other sources. It will allow assessment of compliance with NICE guidance which as described recommends a number of molecular assessments as part of standard practice. NBOCA therefore is requesting to collect additional germline and somatic genomic data from PHE relating to RAS (KRAS and NRAS), BRAF and MMR/MSI.

NBOCA already receive data from PHE, therefore this amendment to CAG sought support for additional data items rather than a new data flow.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG agreed that the amendment was in the public interest. Members noted that it would be helpful to receive further details on the anticipated benefits, in order to support the public interest.

Members noted the request sought access to data from 2017, but also potentially requested data from 12-18 months earlier. The CAG asked that the applicant provide specific clarification on the requested data range. Clarification on whether the original consent obtained for the genetic screening would be sufficient to cover this activity and example of how the outputs from this amendment would be used to improve patient care were also requested.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

1. Specific clarification on the requested data range, to be provided within 10 days of the outcome being issued.

2. Provide clarity on whether the original consent obtained for the genetic screening would be sufficient to cover this activity, within 10 days of the outcome being issued.

3. Provide further examples of how the outputs from this amendment was intended to improve patient care.

4. 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:

   Confirmed: The NHS Digital 19/20 DSPT review for NHS Digital was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (01 June 2021)

4. New applications

a. 21/CAG/0080 – Database of UK recipients of pituitary-derived human growth hormone

Context

Purpose of application

This application from University College London (UCL) set out the purpose of creating a research database which will be used to conduct research into whether people who received injections of pituitary-derived cadaveric human growth hormone (c-hGH) are at risk of developing a disease called iatrogenic cerebral amyloid angiopathy (iCAA).

The applicants intend to update a pre-existing historical database, which is held by Great Ormond Street Hospital (GOSH) and controlled by The Department for Health

and Social Care (DHSC). This database contains information on patients who received cadaveric human growth hormone (c-hGH) treatment between 1959 and 1985. The database includes data on the nature and timing of their treatments. Some of the people who received this treatment went on develop a disease called iatrogenic Creutzfeldt-Jakob Disease. Older versions of this database have previously been used for surveillance and assessment of c-hGH recipients for this disease. Recent research suggests that c-hGH recipients might also be at risk of a newly described disease, iatrogenic cerebral amyloid angiopathy (iCAA). This is a disease associated with strokes caused by bleeding in the brain, as well as seizures (or fits) and cognitive changes. This disease may be caused by transmission of an abnormal protein (called amyloid-beta), and there is evidence that amyloid-beta can be transmitted by c-hGH treatment. As iCAA is newly described disease, the latest version of the pre-existing historical database does not contain information relevant to iCAA, as iCAA was not known about at the time of its latest update. The updated database will be used to confirm whether c-hGH recipients are at risk of iCAA and, if they are, to ensure they can be monitored and receive appropriate clinical care. Clinical care providers and public health bodies can also be updated on this potential risk, in order to make improvements in the care of patients in future.

This pre-existing historical database is held for public health reasons and was created prior to current information governance guidance. The applicants will seek informed consent from patients through contact via their GP, in which they will ask the patients to be involved in research.

The applicants are seeking support for a copy of the data in the historical database to be transferred from GOSH to University College London Hospitals NHS Foundation Trust (UCLH). AT UCLH the data will be converted into an appropriate electronic format, and then disclosed to NHS Digital in order to obtain up-to-date contact details. A contact database will be created and each individual in the contact database will be assigned a newly generated study pseudonymised ID number. A separate key containing NHS number and study ID number will be created. A pseudonymised research database will be created, not containing any items of confidential patient information. The pseudonymised research database will be stored using the UCL Data Safe Haven, and the identifiable contact database and the key will be retained in UCLH.

The applicants will transfer confidential patient information to GP practices using a letter template, in order for the GP to contact the patient in order to consent, using the information sheet and consent forms provided by the applicant. If a patient then consents, the data will be retained in the contact database with consent as the legal basis and all further processing will not require support. If a data subject has emigrated, declines, or does not respond, all identifiers except NHS number will be removed from the "contact" database. A note will be made of their study ID and status in the pseudonymised research database, and the NHS number will be retained alongside the pseudonymous study ID, for the purposes of cross checking. If a data subject is

deceased, they will be included in the pseudonymised research database. Further data will be requested from NHS Digital for these patients on date and cause of death, as well as HES data, and support is required for this. For those that consent, linkage is undertaken with consent as the legal basis. After linkage with NHS digital, all identifiable data except NHS number will be removed from the contact database regarding those who have passed away. Full date of death will be modified for analysis and deleted.

Applicants plan to conduct future research studies in order to investigate this patient group, to ensure they can receive appropriate clinical care to reduce their future stroke risk if they are found to be at increased risk. Identifiable data from the "contact" database will not be released to other researchers. External researchers and research organisations who wish to have access to the pseudonymised research database will need to provide a formal written request detailing which data are required (to be approved by the Data Custodian and Information Guardian) and the purposes for which they will be used, and will require formal HRA ethical approval for their proposed project prior to data sharing. The applicant will additionally discuss any plans for pseudonymised data sharing with the Research Ethics Committee (REC) that has reviewed this application.

A recommendation for class 1, 2, 3, 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	1848 patients whose information was included in a database of recipients of cadaveric human growth hormone between 1959 and 1985, held at Great Ormond Street Hospital for Children NHS Foundation Trust.
Data sources	1. Patient information in a pre-existing database of recipients of cadaveric human growth hormone between 1959 and 1985, held at Great Ormond Street Hospital for Children NHS Foundation Trust. The Department of Health and Social Care (DHSC) are Data Controllers for this database, but as they are unable to hold this data themselves, the database is currently

	located at Great Ormond Street Hospital for Children NHS Foundation Trust (GOSH). 2. NHS Digital – Personal Demographics Service (PDS) 3. NHS Digital – Hospital episode statistics (HES)
Identifiers required for linkage with PDS purposes	1. Name 2. Date of birth 3. Hospital ID number 4. NHS number
Identifiers required as part of contact database (retained with 's251' support before consent provided)	1. Name 2. NHS number 3. hospital ID number 4. GP name and address 5. Date of birth 6. Gender
Identifiers required for analysis purposes	1. Study ID 2. Year of birth 3. Year of death 4. Age at death 5. Gender (This can be considered pseudonymous for analysis)
Additional information	The database will be pseudonymised, with identifiable details separated and held in a different database (contact database). A separate key will be retained between NHS number and Study ID, and will be retained by the applicants. The information in the new contact database is retained with 's251' support, until consent has been provided as the legal basis.

	If the participant has died, emigrated, not responded, or declined, identifying information will be deleted from the contact database, and only NHS number retained in the 'key', with 's251' as the legal basis.

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.

Members felt there were two aspects to this application; one element seemed to be a surveillance exercise, for which the CAG felt there was a medical purpose and was in the public interest, however noting that the study design appeared to limit the validity of this important surveillance element, as described below.

However, the Committee were less clear on the public interest of the second element of the application - the consented research database, noting that the numbers of potential participants are very small and that (c-hGH) treatment is no longer provided. The applicant is requested to provide further justifications for this element, providing examples of research questions as part of a refreshed application.

Whilst this application has been deferred because of the reasons set out below, members wish to encourage the applicants to take advice and resubmit this application.

Scope

The Members had a variety of concerns regarding scope of support. These should be clarified for a future application.

Firstly, the Members wondered if the applicant had discussed with PHE the surveillance element of this application, as it was noted that this is usually a function undertaken by PHE with an alternative legal basis other than 's251' Public Health England: approach to surveillance - GOV.UK (www.gov.uk). The CAG however noted that there are some 's251' supported surveillance applications, and that PHE are possibly unlikely to have capacity

at the present time. The applicant is advised to make contact with PHE to establish if there is any support that could be provided to the applicant in order to undertake surveillance of all the cohort, however it is accepted that PHE may not be able to take this on.

The second concern of the CAG regarding scope was that the design of the study regarding seeking consent for HES linkages seemed to be potentially damaging to the validity of the research. Asking for consent for this step would possibly remove a large proportion of the cohort from the database, as it is very common for a high proportion of a cohort to fail to respond to invitation letters. Once potential participants have been contacted for consent, and not responded, this must be taken as dissent, and the participant can't be asked again, and 's251' cannot override assumed dissent. The "Managing non-response: establishing the ICO and CAG position" published by the HRA comprehensively sets out this position.

Essentially, where consent is sought by the applicant, "section 251" support to access the confidential patient information of the living, without consent, cannot be given where individual does not respond to the request. The applicants are providing information to potential participants about both linkages with HES; joining the research database and potentially providing genetic material, and requesting consent for each of these elements. The applicant is not requesting support for those who do not respond, but considering this may actually be a large proportion of living participants, the Group did feel that the validity of the research would be compromised, as the cohort is small, and there may be many non-responders.

The group advises the applicants to consider this aspect of the study carefully and how to proceed. One alternative would be to consider separating the consent aspects into two, and separately using 'section 251' support for linkage of the database to PDS, and HES data on inpatient and outpatient hospital care for neurological symptoms and diseases (for the entire cohort) and seeking consent through the GP for donating genetic material, or other further involvement for the research database, or a specific research study.

If this route was considered, the applicants need to (a) be clear about this in their scope, (b) update the patient information materials accordingly, notifying about the linkages undertaken with HES and PDS, and providing an opt out option, rather than using a consented opt-in approach, and (c) provide justification why consent for use of data is not practicable.

The final element regarding scope of support was the clarity of the data flow diagram. The Members noted that despite clarity in the answers provided in the (Confidentiality Advice Team) CAT advice form, the data flow diagram was misleading, for example, if a patient emigrated, this information would be identified in information received from NHS Digital, rather than from the GP, as it appears from the diagram. In a future

application, the group felt that the data flow diagram should be made clearer, identifying data flows that require support, and identifying organisations between which data is flowing.

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 will be contacted for consent. Patients who are deceased cannot consent. It would be impossible to ask for consent without first confirming the details for the named individual; the pre-existing historical database does not contain enough information to do this. The CAG commented that the justification for not seeking consent was appropriate, however conversely, they suggested that in this case it may not be appropriate to seek consent for the HES linkages to be undertaken, (see further detail in section on scope).

- Use of anonymised/pseudonymised data

Confidential patient information is required to link data from the pre-existing database to datasets held by NHS Digital, and will be pseudonymised for analysis. The applicant has confirmed they wish to retain NHS number in order to prevent further contacts for those who have passed away, emigrated, not responded or declined. It was agreed by that the use of anonymised/pseudonymised data is impracticable for the linkages requested, and the applicants are unable to complete these without confidential patient information. However, it was commented that it was not clear why the NHS number was required to be retained alongside the pseudo ID indefinitely, and the applicant is asked to further justify this (see further detail in section on exit strategy).

‘Patient Notification’ and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for

reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants will contact the GPs of patients who are still alive and who are living in the UK. This contact will be made by post, telephone or both. The applicants will ask the GP to confirm that the patient has been correctly identified and to share the information sheet, consent form and privacy notice with the patient. If required, applicants will generate a person-specific version of our information and consent form that meets their special communication needs. This might include translations of printed material and the use of an interpreter. The information sheet and consent form are provided.

However, as the breach in the common law duty of confidentiality is undertaken prior to the receipt of the information sheet, the applicants will provide mechanisms for opt-out prior to the initial linkage with PDS. The proposed work will be advertised via a study-specific webpage on the MRC Prion Unit at UCL webpage (not yet set up), which will include links to the Participant Information Sheet and UCL Privacy Policy (provided). It will be linked to webpages for the MRC Prion Unit at UCL (https://www.ucl.ac.uk/prion/) and the National Prion Clinic (https://www.ucl.ac.uk/national-prion-clinic/). Details will be provided for the study contact so that people who believe they are pituitary-derived human growth hormone recipients can get in touch, either to participate or to opt out. A statement for the webpage was included in the query responses.

The national data opt out applies. An option to opt out of the processing prior to letter being sent is available via the study website. Additionally, participants can opt out of being included in the database (which includes linkage to HES).

It was commented that the patient notification provided was written in quite sophisticated language. This should be amended to ensure a lay person can understand, and the Members suggested a review of the patient notification materials by a patients and public involvement group.

It was also noted that neither the legal basis for processing confidential patient information in order to contact the patients ('s251 support'), or the role of the CAG had been explained in any of the patient facing materials.

Members felt the opt out options provided were well thought through and seemed appropriate.

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 CJD Support Network was originally created by relatives of people who have died with Creutzfeldt-Jakob Disease (CJD), and is now the leading UK charity for all forms of CJD. Applicants held a focus group meeting on May 4th 2021, to discuss the proposed research plans, and have provided the presentation to the CAG. A supportive letter from the CJDSN Committee has been provided, raising no issues with the methodology, and seems to support this use of confidential patient information in order to seek consent. Applicants will also be speaking to people with iCAA to ask their views on this database and its policies (but this has not yet been undertaken). Applicants plan to facilitate the creation of a specific support group for these data subjects, however it has not yet been possible, as the applicants have not as yet been able to contact the participants.

The Members noted the work that had been undertaken, however it was felt that the response from the CJDSN did not explicitly support the use of confidential patient information without consent. For a future application, the applicant should provide further details surrounding responses detailing the use of confidential patient information without consent. The applicant should also continue to undertake further Patient and public involvement activities, as is described in their application, and this should be taken as an opportunity to review the patient facing materials as described in the patient notification section.

Exit strategy

For those that consent, consent will be the exit strategy. For those who are deceased, decline consent, do not respond, or have emigrated, ongoing support is required until NHS number is deleted. (retained for cross checking). The applicant estimates they may be ready to delete all identifiable information by February 2025, however it is not certain as the research database may be being used by a separate project at that time. Therefore, support for research database to be requested for 5 years in line with the REC.

The CAG members were unclear as to why the NHS number (as part of the key with the pseudo ID) is required to be retained indefinitely for those that decline, do not respond, or emigrate, as the result is that ongoing support is required. Could the information regarding status be fed back to the original database, and the applicant

could then delete the NHS number? Further justification is therefore required for retention of the NHS Number, as there is currently the need for ongoing support despite no identifying information being required for analysis and no further linkages required.

Legal basis of database as data source

DHSC are in the process of confirming the legal basis for the retention of the historical database and have been in touch with CAT regarding this. There is a precedent for the use of this dataset in a CAG application, 15/CAG/0112. The applicant is not the organisation retaining the data or the data controller, and as such cannot request CAG support for ongoing retention of the historical database. Applicants will not be able to undertake the research without a data sharing agreement with DHSC as the data controller, and this may be established after CAG support is in place.

The Committee noted that the legal basis of the historical database would need to be established with DHSC before final CAG support could be provided, however provisional support could be considered. The CAT team are working with DHSC to establish a legal basis, and the applicant could submit a future refreshed application before this has been concluded.

Access to research database

It was noted by Members that the data collected in the database could be used by researchers applying and having their request considered by the Data Custodian and Information Guardian. The applicant should consider having lay representation on a data access committee to consider research applications to the database.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Following advice from the CAG, the Health Research Authority recommended that the application was deferred.

Request for further information

1. Please provide further clarifications on the public interest in creating this research database, providing examples of how answers to specific research questions would be in the public interest.

2. The applicant should make contact with PHE regarding advice around undertaking the surveillance element of the application.

3. Consider the impact of the “Managing non-response: establishing the ICO and CAG position document”, and how to take forward this when considering the scope of support requested.

4. Consider clarifying and simplifying the flow charts to demonstrate where support is required, and the data flows involved. Consider splitting these out into simplified flows for each aspect that requires support.

5. Please provide further justification regarding the retention of the NHS number alongside the pseudo-ID for those that declined, did not respond, or emigrated.

6. The patient notification should be reviewed to use less sophisticated language to ensure a lay person could understand it, and these materials should be reviewed by a patient and public involvement group.

7. The legal basis for processing and the role of CAG should be explained in the patient notification materials.

8. Further patient and public involvement evidence should be provided regarding the use of data without consent, and further ongoing patient and public involvement work should be undertaken.

9. A legal basis for the retention of the historical database should be established by DHSC before final ‘s251’ support could be provided.

10. Consider lay representation on a data access committee to review research applications to the database.

11. Ensure NHS Digital has reviewed the DSPTs for all required organisations; University College London Hospital NHS Foundation Trust, NHS Digital, and

Great Ormond Street Hospital NHS Foundation Trust. GOSH currently has a pending review.

b. 21/CAG/0078 – Cancer Survivorship Studies

Context

Purpose of application

This application, from University of Birmingham, sets out the purpose of medical research that aims to establish a research database by combining two research databases, The British Childhood Cancer Survivor Study and The Teenage and Young Adult Cancer Survivor Study.

By 2030 it is estimated that there will be 4 million individuals living with the long-term consequences of cancer and its treatment. Recently there have been three UK-wide research priority setting initiatives involving detailed consultations with cancer patients/survivors, their families and friends, and health care professionals who treat or follow-up individuals who are living with or beyond cancer. Half of the final top 10 research priorities ultimately identified related to an issue concerning “cancer survivorship”, that is concerns which relate to problems encountered after cancer treatment is completed and the survivor returns to ‘normal’ life. The linkage of large-scale population-based cancer survivors cohorts to electronic health care databases provides a unique opportunity to investigate the risks of a wide spectrum of long-term adverse health outcomes following treatment for cancer on a national level.

The applicants request to combine two research databases currently operating under Regulation 5 support; The British Childhood Cancer Survivor Study (BCCSS - ECC 2-02(f)/2011) and The Teenage and Young Adult Cancer Survivor Study (TYACSS - ECC 3-04(c)/2010). Confidential patient information will flow from the University of Birmingham to link to a number of datasets detailed in the data sources section. These are a combination of national datasets, those operating under consent or others operating under CAG support. Linkage will be undertaken on an annual basis. Clinical data will be flowed back to University of Birmingham to create the database.

Researchers requesting access to the database will submit a research proposal that will be reviewed by the chief investigator and Senior Researchers who may consult with patient representatives to assess whether the research is relevant and important to cancer survivors.

Following support for this application the British Childhood Cancer Survivor Study (BCCSS - ECC 2-02(f)/2011) and The Teenage and Young Adult Cancer Survivor Study (TYACSS - ECC 3-04(c)/2010) will be expired.

A recommendation for class 1, 2, 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	The British Childhood Cancer Survivor Study (BCCSS) - 35,000 individuals who were diagnosed with cancer under the age of 15 years, between 1940 and 2006, in England, Wales or Scotland, and who survived at least 5 years from diagnosis. The Teenage and Young Adult Cancer Survivor Study (TYACSS) - 200,945 individuals diagnosed with cancer when aged 15 to 39 years inclusive, between 1971 and 2006, in England or Wales and who survived at least 5 years from diagnosis.
Data sources	4. University of Birmingham: a. British Childhood Cancer Survivor Study (BCCSS - ECC 2-02(f)/2011) b. The Teenage and Young Adult Cancer Survivor Study (TYACSS - ECC 3-04(c)/2010) 5. NHS Digital a. National death registries (ONS Mortality datasets) b. National cancer registries c. Hospital Episode Statistics (HES) d. The National Mental Health Services Dataset 6. Public Health England a. National NHS GP prescription database b. National Systemic Anti-Cancer Therapy Dataset c. National Radiotherapy Dataset d. National Diagnostic Imaging Dataset e. National Congenital Anomalies and Rare Disease Registry (CAG 10-02(d)/2015) 7. Digital Health & Care Wales (DHCW) (Formerly known as NHS Wales Informatics Service, (NWIS)

	a. Patient Episode Database for Wales (PEDW) 8. Barts Health NHS Trust a. National Institute for Cardiovascular Outcomes Research (NICOR) - Various Cardiovascular outcomes datasets (17/CAG/0078) 9. Birmingham Women's and Children's NHS Foundation Trust a. West Midlands Regional Children's Tumour Registry (17/CAG/0103) 10. British Society of Blood and Marrow Transplantation and Cellular Therapy a. BSBMTCT Data Register (held under consent)
Identifiers required for linkage purposes	5. Name 6. Gender 7. Date of Birth 8. NHS number 9. Post Code 10. (Random Key)
Identifiers required for analysis purposes	1. Date of birth (month and year only) 2. Date of death (month and year only) 3. Postcode (unit level) 4. Gender 5. Ethnicity 6. Date of cancer diagnosis (month and year only)

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 Members agreed that there was an appropriate medical purpose that is in the public interest.

Scope

It was commented by the CAG that the statement ‘emerging linkages’ had been used, and it may be that new datasets arise which the applicant would like to undertake additional linkage with. In these cases, an amendment to CAG support is required, as support provided is for specific datasets.

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 state the combined cohorts include data on over 240,000 survivors of cancer, and consent will not be feasible. They also state that as a population-based study there is a need to avoid selection bias, which consent may introduce. Both cohorts are already supported under previous CAG applications. The Committee agreed that consent was not a practicable alternative.

- Use of anonymised/pseudonymised data

Confidential patient information is required to link to the requested databases and is not achievable with anonymised/pseudonymised data only. Confidential patient information will be transferred only once alongside a linkage key. This will be kept by the organisations so that future data provision will not need a transfer of identifiable information from University of Birmingham. No identifiable data will be held within the research database – this will be held separately alongside the key. Any dates in the database (such as date of birth, date of death and cancer diagnosis) will be reduced to month and year only. No identifying information will be shared with researchers accessing the database. The Members agreed with the justifications provided for the use of confidential patient information.

‘Patient Notification’ and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient

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

In response to queries the applicant advised that '*The study protocol will be available on the study website for patients to access. In addition, a specific section on the website will contain information on how patients can opt out*". An '*opt out website'* document is provided to enable a study specific opt out mechanism. The national data opt out will also be applied.

The CAG commented that although the protocol on the website may be of interest to patients, this is not an adequate mechanism of notifying patients about how their confidential patient information is being processed without their consent. A separate patient notification document does need to be developed which provides a clear description of the study purposes and processes. The opt out website document does not provide this level of detail, as it is limited to text in relation to the opt out and does not contain wider information on the study. It was noted that the University privacy notice was mentioned, however this also does not provide any detail relating to the application.

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 application provides full details on the patient and public involvement that has been undertaken. There appears to have been high engagement with patients and the public, with two members invited to sit on the project steering group. The applicants state that '*Through the several PPI groups we have raised the acceptability of processing identifiable patient data with consent. Generally, the support for conducting this study has been positive and no concerns regarding processing identifiable data were raised.'*

The Committee felt that although a lot of patient and public involvement had been undertaken with multiple organisations over many years, it was not clear if much work had been undertaken regarding this specific application, and the processes involved. Further patient and public involvement should be undertaken specifically surrounding the purposes and data flows involved in this specific application.

Exit strategy

This application is designed as a research database, that may require further linkages in the future. The applicants state that *'Identifiable data will be securely destroyed at study completion, but it is difficult give a precise end date for the study as the entire linkage process has not been undertaken before.'* Support has therefore been provided for five years in line with the REC. if support is required after five years, a duration amendment will be required. As noted in the scope section above, any future linkages with different datasets will also require an amendment to CAG support.

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 request for further information, within one month.

Request for further information

1. Please develop a patient notification document which is specific for this application, which describes the study purposes, processes, and describes how to opt out. Please provide this to the CAG for review.

Specific conditions of support

The following sets out the specific conditions of support.

1. Previous applications, The British Childhood Cancer Survivor Study (BCCSS) – ECC 2-02(f)/2011 and The Teenage and Young Adult Cancer Survivor Study (TYACSS) - ECC 3-04(c)/2010, will be expired from the date of the final outcome letter, and replaced by 21/CAG/0078.

2. Support is in place for five years from the date of the final outcome letter, in line with the REC. Further support is to be sought after this time, via a duration amendment.

3. Support only extends to England and Wales.

4. Continuing patient and public involvement should be undertaken, to specifically explore the purposes and data flows involved in this specific application, and a report should be provided to the CAG within six months from the date of the final outcome letter.

5. Favourable opinion from a Research Ethics Committee. **Confirmed 23 February 2021.**

6. 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: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for the following organisations have been assessed as 'standards met' by NHS Digital;**

   - **University of Birmingham**
   - **Public Health England**
   - **NHS Digital**
   - **Birmingham Women's and Children's NHS Foundation Trust (WM cancer registry)**
   - **British Society of Blood and Marrow Transplantation and Cellular Therapy**
   - **Barts Health NHS Trust**

   - **A CPiP assessment is in place for NWIS.**

c. 21/CAG/0074 – CQC 2021 Community Mental Health Survey - Mixed Methods stand-alone pilot

Context

Purpose of application

This non-research application submitted by Ipsos MORI on behalf of the Care Quality Commission, set out the purpose of administering the 2021 Community Mental Health Survey - Mixed Methods stand alone pilot. The community mental health mainstage survey has previously been conducted using a postal approach. However, this pilot

study will test the effectiveness of a mixed methods approach, offering the questionnaire online (in addition to a postal survey), and sending SMS reminders (in addition to postal reminders).

The community mental health Survey falls within the NHS Patient Survey Programme (NPSP). The NPSP was initiated in 2002 by the then Department of Health, and is now overseen by the Care Quality Commission (CQC), the independent regulator of health and social care in England.

Ipsos MORI will select 21 Trusts for inclusion in the pilot with the aim of 20 trusts completing it. Trusts will collect information of all eligible patients and, following suitability checks, will share confidential patient information with the coordination centre (IPSOS MORI). The sample for each trust will be split into a "control" group and an "intervention" group. The "control" group will receive the survey as they would for the current Community Mental Health Survey design (a paper questionnaire only). Those in the "intervention" group will receive a different mailing strategy designed to encourage them to take part online – this will also include SMS messages. A postal questionnaire will be available to all patients. All fieldwork will be conducted by the Coordination Centre for Mixed Methods (based at Ipsos MORI). This differs to the main survey where NHS trusts may opt to undertake the mailing of questionnaires themselves or to employ an approved survey contractor to administer the survey on their behalf.

IPSOS MORI will distribute questionnaires to patients using the approach detailed below;

The intervention group will receive;

Contact 1: Letter + URL link for online questionnaire

Contact 2: SMS despatched 7 days later +URL link for online questionnaire

Contact 3: Contact 1 +2wks, 50% letter +URL, 50% letter +URL +paper questionnaire

Contact 4: SMS despatched 7 days later +URL link for online questionnaire

Contact 5: Contact 3 +2wks, letter with paper questionnaire (no URL)

The control group will receive the same number and style of contacts as the 2021 Community Mental Health Survey approach:

Contact 1: Letter with paper questionnaire

Contact 2: 1 week after contact 1, reminder letter

Contact 3: 2 weeks after contact 2, reminder letter with paper questionnaire

Ahead of each reminder, it will be necessary to remove all respondents who have completed the survey already, and to conduct a DBS or local check on the full sample. If anyone has requested to be opted out of further reminders, they should also be removed at these timepoints.

A recommendation for class 5 & 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	Patients aged 18 and over who had been in contact with NHS mental health services in the three-month period from 1st May 2021– 31st July 2021, and who were receiving specialist care or treatment for a mental health condition, including those who receive care under the Care Programme Approach (CPA) • Who were seen by someone face-to-face at the trust or via video conference (e.g. using Attend Anywhere, MS Teams, Zoom etc) or telephone call between 1st May and 31st July 2021 (the sample period); **AND** • had at least one other contact (face-to-face, video conference, phone or email) either before, during or after the sampling period 760 service users from 20 Trusts. (a total of 14,000)
Data sources	11. Electronic patient records, Mental Health Trusts in England
Identifiers required for contact purposes	11. Trust code 12. A standardised unique identifier code, 13. Title (Mr, Mrs, Ms, etc.) 14. First name 15. Surname 16. Address Fields 17. Postcode 18. Mobile phone number where available

Identifiers required for analysis purposes	7. Trust code 8. The unique identifier code (as above) 9. Year of birth 10. Postcode 11. Gender 12. Ethnic category 13. Day of last contact 14. Month of last contact 15. Year of last contact 16. CPA status 17. CCG code 18. Mental Health Care Cluster Codes 19. Mode of contact since 1st March 2020 20. Postcode (mapped to Lower Layer Super Output Areas to allow analysis by deprivation and region, then securely deleted)

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Members were agreed that this activity represented an appropriate medical purpose which is in the public interest. It was noted that it is important to gain feedback from service users to seek to improve mental health services, and the committee understood the need for continuously piloting new mixed methods to ensure the maximum possible return is gathered from the questionnaire.

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.

- Minimising flows of identifiable information

It was noted that although Ipsos MORI will be conducting the pilot on behalf of the CQC, the mainstage survey is still being undertaken by Picker Institute. The applicant had commented on the slim possibility of Trusts therefore potentially sending identifiable data to the incorrect organisation in error. The CAG assume that Ipsos MORI had made this clear in the instructions provided to the Trusts, and that the likelihood of a breach occurring was minimised. However the Members would like some assurance of the process that will be followed if a Trust does send confidential patient information to Picker rather than Ipsos MORI, for example, Picker would immediately delete the information, and the applicant would notify CAG that a breach had occurred.

- Feasibility of consent

The applicant has presented three central arguments as to why consent is not practicable, which have been accepted across the National Survey Programme. These include the potential to introduce bias into the survey findings, and the potential burden on clinical staff through the requirement to take consent.

The Members were content with the justifications provided and agreed consent was not a practicable alternative.

- Use of anonymised/pseudonymised data

Confidential patient information is required to facilitate the invitation process which could not be otherwise achieved. For analysis, postcode is deleted after mapping to LSOA and local authority, as per other surveys.

The CAG were content that this activity could not be undertaken without the use of confidential patient information.

Justification of identifiers

The CAG members discussed the data items collected surrounding ethnicity. It was noted that the classification categories were perhaps not detailed enough, and therefore would potentially not be useful data items to collect, despite being special category

data, as the categories may be too broad for people to choose which they fit in to. It was thought that more detailed specifications would make collecting this data item more useful. The Members noted that it is not within the applicants' gift to alter the ethnicity coding currently used within the UK, and therefore there are no conditions or further information required associated with this comment. It was however a discussion point, and as such has been included in this outcome letter.

'Patient Notification' and mechanism for managing dissent

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

Posters will be displayed in participating Trusts throughout the sampling period to inform patients that they may be approached to participate in the survey and provide a means for prior dissent to be raised. These have been produced in English only for the pilot. Trusts are asked to consider the impact of Covid-19 on the visibility of posters, and to think carefully about where to place them appropriately. Trusts have also been advised to display a copy of this poster on their website for those service users who do not frequently attend the trust premises. Although the provision of posters is the primary method of informing the study population of the survey, Trusts will also be encouraged to undertake their own additional promotional activities, for example through press releases and local social media, and In addition to the dissent poster, a press release and social media text have been drafted, and can be found in the survey handbook. Although the current sampling period has already begun (1st May – 31st July 2021) the Trusts have already been asked to display these posters (as per other CQC surveys). The poster provides information about how a patient can opt out of the survey. Trusts are also asked to remove any records where existing dissent has been recorded. The surveys have exemption from the national data opt out.

The Committee were content with the notification and opt out options provided.

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 application form provides a detailed overview of the patient and public involvement in the development of this survey. For this pilot, interviews were conducted with nine potential service users to test the approach and the materials, along with how service users feel about being contacted by SMS. A further three interviews were conducted with stakeholders of mental health charities. Across the interviews the pilot methodology of offering online completion and contacting service users by SMS was considered acceptable. The use of confidential patient information without consent was specifically discussed in nine interviews completed with potential service users. Participants were not concerned about personal information being shared for this purpose. The nine potential service users were also shown examples of the survey materials including draft covering letters which included an explanation of how their contact details were passed to Ipsos MORI. No concerns were raised by participants upon reviewing these letters.

The CAG were content that sufficient patient and public involvement had been undertaken.

Exit strategy

The publication date is likely to be in March/April 2022. The sample/contact details will be deleted by 01 May 2022, and support is required until that point.

The Members were content with this exit strategy.

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 Secretary of State for Health and Social Care 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. Please provide evidence of NHS Digital review of the DSPT for Ipsos MORI (standard condition of support, below).

Specific conditions of support

The following sets out the specific conditions of support.

1. Please provide assurance to CAG of the process that would be followed should a Trust send confidential patient information to Picker in error, and that participating trusts were aware of this process, within one month from the date support provided.

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. **Pending:**

   The NHS Digital **19/20** DSPT review for **Ipsos MORI** was pending

d. 21/CAG/0076 - Configuration and utilisation of clinical pathways by patients who attend A&E in suicidal crisis

Context

Purpose of application

This application from Liverpool John Moores University sets out the purpose of medical research that aims to gain an understanding of how visits to A&E for self-harm, suicidal ideation and crisis are coded, and whether the pathways of care are consistent at each A&E site. This study will explore suicidal crisis data at A&E level and will test feasibility across two trusts with the aim of developing a national data collection tool for A&E departments to record people who attend in suicidal crisis. This study requires CAG support for phase one only, phase two is out of scope for CAG support.

Suicide is a major public health issue. Although national data is available for individuals who attend A&E for self-harm and suicidal injury, there is no national data for those individuals who attend A&E in suicidal crisis. The clinical pathways available for service users after presentation in suicidal crisis are complex and have not been

examined systematically. Gaining a greater insight into the configuration and utilisation of clinical pathways for service users in suicidal crisis will better inform modelling of service provision for these patients.

The initial identification of potential participants medical notes, using the electronic databases at each of nine A&E sites, will be undertaken by the direct care team who will inform the researcher. The named researcher, who is not a member of the direct care team, will have on-site access to patient medical records, which include confidential patient information. Retrieving information will be a time-consuming activity, and the direct care team have indicated that they do not have the time and resources to complete this work. Therefore CAG support is required. Potential participants will be screened by the named researcher, and if eligible, pseudonymised data will be recorded. Although a key is retained between the NHS number and the unique anonymised study ID, this is retained by the direct care team only. Therefore support is not required for this retention, and the collected dataset can be considered anonymous to the named researcher. No confidential patient information will be recorded or retained by the researcher. Data will subsequently be analysed at Liverpool John Moores University.

A recommendation for class 1 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	Individuals aged 16 and over who have attended A&E in suicidal crisis between January 2019- December 2020. (people who may have presented in suicidal crisis, for self-harm or following suicide attempts) sample size of 1200 (approximately 133 per site)
Data sources	• Electronic databases at 9 A&E departments, and associated Trust medical records Cheshire and Wirral A&E sites are: 12. Arrowe Park,

	13. Countess of Chester Hospital, 14. Macclesfield District General Hospital, 15. Leighton Hospital. Mersey Care A&E sites are: 16. Royal Liverpool University Hospital, 17. Aintree University Hospital, 18. Southport and Formby District Hospital, 19. Whiston Hospital, 20. Warrington Hospital
Identifiers required for data extraction purposes	19. Researcher will view medical notes to extract a pseudonymised dataset 20. Hospital ID 21. NHS number 22. Unique anonymised study number
Identifiers required for analysis purposes	1. Age 2. Gender 3. Ethnicity 4. Education 5. Employment status 6. Has the patient had COVID-19 7. Unique anonymised study number It is not possible for the researcher to re-identify a patient from this data extract.
Additional information	A key that will be held within each Trust linking NHS number to a unique anonymised study number. If researcher MM needs to go back to a patient file this key will allow re-identification, however only the Trust would hold this information. No identifiable data will be held by the researcher.

Confidentiality Advisory Group advice

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

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The CAG agreed that this application has a medical purpose that is in the public interest. However the definition of suicidal crisis had not been clearly provided, and Members were unclear on the exact definition of suicidal crisis and how this relates to the other clinical contexts/diagnoses relating to suicide that are mentioned in the application.

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.

- Minimising flows of identifiable information

It was noted by the CAG that some of the data collected in the proforma, specifically the mental state examination and the physical examination sections, could involve the collection of free text information, which could potentially contain very detailed identifiable information. However, the Members were unclear if free text information would be recorded, or if these questions were simply recording if a mental state examination or physical examination had been undertaken, and a simple yes or no would be recorded. The Committee therefore required some assurances that the researcher would not be recording any identifiable patient information, in any way, in these sections of the proforma.

The CAG also discussed if there were any safeguards in place at each Trust to ensure that the researcher was only extracting the information described in the application and not any identifiable information or any additional information from the medical notes. However these local procedures are out of CAG remit and are covered by the HRA approval process, and as such there are no requests for further information surrounding this.

- Feasibility of consent

The applicant reasons that it would not be practicable to seek consent for this study, due to a large sample size. The time required to locate and make contact with the patients would be prohibitive. The Committee were content with this justification and agreed consent was not a practicable alternative.

- Use of anonymised/pseudonymised data

It is not possible to extract an anonymous sample from medical records without viewing confidential patient information, and the dataset will be effectively anonymous to the researcher at the point of data extraction. The CAG agreed that data extraction could not be undertaken without viewing confidential patient information.

- Trust IT department involvement

It was noted by the Members that in some applications it is possible for Trust IT departments to extract an anonymised clinical dataset. This would avoid the breach in the common law duty of confidentiality if this was possible in this application. However, the Committee considered that this was unlikely, as the application is exploring clinical coding difficulties (which any data extraction would be based on), and it is also likely that A&E notes would be paper medical records rather than electronic, which would make an electronic extract impossible, as the paper notes would have to be manually viewed. However, as this is not absolutely clear from the application, the applicant is requested to confirm whether the records being considered are electronic, and if so, that a potential anonymised extraction has been discussed with the Trust IT departments and is not a practicable alternative.

'Patient Notification' and mechanism for managing dissent

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

A patient notification has been provided, which will be displayed on the study webpage on Liverpool John Moores University site. This will also be displayed on Cheshire and Wirral Partnership's website. It contains a study specific opt out option, which has been viewed by the Patient and Public Involvement (PPI) group and deemed appropriate. Individuals can opt-out via the webpage, email, phone or post. The national data opt out will apply.

The Members commented that the notification document used quite complex language, and requested that the applicant re-word the document using more lay language. The CAG were content with where the notification is planned to be displayed.

The local opt out mechanism will be implemented using confidential patient information, however this is provided with the consent of the person opting out for their data to be used for the purpose of opting them out. It is assumed that the researcher will delete the identifiable information of those who opt out after removing them from the dataset, however this is out of the remit of CAG, and no further information is required.

The CAG members accepted that the national data opt out would be applied, but wanted further confirmation from the researcher that this would be applied using MESH by the direct care team at the Trusts before providing the researcher with a list of eligible patients, as per guidance on the NHS Digital website.

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.

A service user advisory group has been formed comprising of individuals who have attended A&E in suicidal crisis across both Cheshire and Wirral Partnership and Mersey Care NHS Trust. Members so far include 3 female and 2 male service users. Recruitment is still ongoing to expand the service user advisory group. An initial meeting via Zoom (15 April 2021) was undertaken to gauge the views of the service user advisory group on the acceptability of using confidential patient information without consent for the research methodology. The group was supportive of this. Involvement of the service user advisory group will continue throughout the course of the study, in a variety of ways as described in the application. Meetings will take place 3-4 times per year. Views and feedback from service users will be considered at each stage of the project. Meetings with clinical staff working in A&E, as well as service users who have attended A&E in suicidal crisis will continue to inform the development of a questionnaire proforma.

The members were content that the patient and public involvement undertaken was sufficient.

Exit strategy

The researcher will be accessing data on-site to extract effectively anonymised data. The exit strategy is anonymisation of the data set. No identifiable data will be held by the researcher. The applicant estimates this will be undertaken over a two year period, and CAG support is therefore required for the two year duration. The CAG was content with this exit strategy.

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. Please provide a definition of suicidal crisis, and explain how this relates to the other described clinical contexts surrounding A & E attendances relating to suicide.

2. Please clarify what information is being recorded in the proforma as part of the mental state examination and physical examination sections, and provide assurance to the CAG that this will not be identifiable data.

3. Please confirm that Trust IT departments extracting an anonymised dataset for the researcher is not a practicable alternative, and provide justification to CAG.

4. Please provide an updated patient notification which is written in less complex language.

5. Please confirm that the national data opt out would be applied via MESH by the local Trusts.

6. Please provide evidence of NHS Digital review of the DSPT for Cheshire & Wirral Partnership NHS Trust (standard condition of support, see below).

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 27 May 2021**

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. **Pending:**

   The NHS Digital **19/20** DSPT review for **Mersey Care NHS Foundation Trust** was confirmed as **'Standards Met'** on the NHS Digital DSPT Tracker (checked 16 June 2021)

   The NHS Digital DSPT review for **Cheshire & Wirral Partnership NHS Trust** is pending.

e. 21/CAG/0077 - Classification of breast cancer for personalised therapy

Context

Purpose of application

This application, from University of Nottingham sets out the purpose of medical research that aims to determine key mechanisms, roles and drives controlling breast cancer behaviour and prognosis.

Over 56,000 women are diagnosed with breast cancer in the UK each year. About a third of patients develop an aggressive form of breast cancer and can die earlier. Some forms of breast cancer do not respond well to drugs.

The applicants wish to build upon a current study (19/CAG/0084) by using 6000 cases from Sherwood Forest Hospitals NHS Foundation Trust. Members of staff from University of Nottingham and Sherwood Forest Hospitals NHS Foundation Trust, who are not considered part of the direct care team, will access confidential patient information at Sherwood Forest Hospitals NHS Foundation Trust to identify the patient cohort and collect information from the medical records. These will be sent to University of Nottingham in a pseudonymised manner to allow further research alongside tissue samples from the patients.

The applicants will use the tissue and associated clinical and outcome data to refine the criteria of breast cancer diagnosis and grading in the era of digital pathology, to use computational pathology and machine learning and artificial intelligence to evaluate various morphological features in breast cancer and to interrogate publicly available molecular datasets to utilise gene expression microarrays and next generation sequencing which provide data on tens of thousands of genes. The applicants intend to identify novel targets for further investigation and validation using tissue microarray technology and different analytical techniques.

A recommendation for class 1 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	6000 consecutive male and female patients, presenting at Sherwood Forest Hospitals NHS Foundation Trust between 1st January 2000 and 31st December 2015 with breast lesions who had surgery for diagnostic purposes.
Data sources	21. Sherwood Forest Hospitals NHS Trust

Identifiers required for linkage purposes	23. Date of birth 24. Hospital Number 25. Gender
Identifiers required for analysis purposes	21. None
Additional information	Gender will be retained for analysis purposes, and date of diagnosis will be converted to age at diagnosis.

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 Committee agreed that this application had an appropriate medical purpose and was in the public interest.

Scope

The CAG requested clarification on who was actually undertaking the extraction of the data, as a few different individuals are mentioned in the application, but it appeared that the scope of ‘s251’ support was potentially only for one individual, a lab assistant, to undertake data extraction.

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 research is using data from 6000 patients between 2000 and 2015. The applicants state that the large sample size and retrospective nature of the study make consent impracticable. Given the disease area many patients may have died or moved out of the area. The applicants also confirm that patients would not have consented to use of the tissue in research at the time of surgery. The CAG Members were content that consent was not a practicable alternative.

- Use of anonymised/pseudonymised data

The researchers at University of Nottingham will only have access to pseudonymised data. Support is needed for data collection from the Trust, for which access to identifiers is necessary and will be undertaken by those outside the direct care team. The CAG agreed that this could not be undertaken in any less disclosive manner.

'Patient Notification' and mechanism for managing dissent

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

The applicants have been working with the engagement team at Sherwood Forest Hospitals NHS Foundation Trust on a plan for dissemination of information on the research activity. This will include posters, leaflets and talks at public meetings, and clinicians who have direct contact with patients, and who are also collaborators in this study, distributing leaflets to patients attending breast clinics and explaining to patients how to opt out if they wish.

A leaflet and poster were provided for consideration. Whilst the poster appears to be study specific, the patient leaflet is a generic one informing patients about the wider work of the group – this includes a reference to Google which is not applicable to this application. The provided patient leaflet and poster provide a local opt out mechanism and the national data opt out will be applied.

The Members noted that although there is some clarity in the description of the research activity in the notification, that there should be a study specific leaflet rather than a

generic one, and references to Google and other non study specific processes should be removed.

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 provided a support letter from an individual who was supportive of the applicants plans for communicating and engaging with the target groups. The applicant advised that patient and public involvement is at an early stage. Whilst the support letter has been provided, alongside references to supportive patient and public involvement undertaken as part of 19/CAG/0084, the group plan further activity which will include and discuss the acceptability of using identifiable data without consent for purposes described in the application.

The Group were content to recommend support on the basis of the patient and public involvement provided, but a condition of support has been applied to ensure that further activity is undertaken, specifically around the acceptability of the use of confidential patient information without consent for the purposes of this specific application.

Exit strategy

Once the data collection is complete researchers at the University of Nottingham will have access to pseudonymised data only. A master file containing the key and personal data will be held at Sherwood Forest Hospitals NHS Trust. The application states that the research is expected to last 5 years, and the master file kept for 6-12 months after this. The applicant indicates in the advice form that support is required for 12 months after the end of the study, a total of 6 years.

The Members were content with this exit strategy.

Previous application

The Committee requested clarity on whether the dataset collected under this application would be combined with the dataset from the previous application, 19/CAG/0084.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, 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

The following sets out the specific conditions of support.

1. Please clarify which individuals are actually undertaking the data extraction, to be clear on the scope of support required under Regulation 5, and provide a response to CAG within one month from the date of this letter.

2. Please clarify whether the dataset collected under this application would be combined with the dataset from the previous application, 19/CAG/0084, and provide a response to CAG within one month from the date of this letter.

3. A study specific patient notification leaflet should be developed, and all references to Google should be removed. Please provide an updated version of this notification to the CAG within one month from the date of this letter.

4. Please undertake further patient and public involvement activity, specifically around the acceptability of the use of confidential patient information without consent for the purposes of this specific application, and report back to the CAG within six months from the date of this letter.

5. Favourable opinion from a Research Ethics Committee. **Confirmed 27 May 2021**

6. 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 **19/20** DSPT reviews for **University of Nottingham** and **Sherwood Forest Hospitals NHS Foundation Trust** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 16 June 2021)

5. Minutes of the meeting held on 21 January 2021

The minutes for the following CAG meetings have been ratified via correspondence and are notified for information at this meeting:

Full CAG meetings: 21 January 2021

6. Any other business

No other business was raised.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date
Minutes signed off via correspondence by Dr Patrick Coyle, CAG Vice Chair, and Ms Clare Sanderson, CAG Alternate Vice Chair	12/10/2021
Signed – Confidentiality Advice Team Katy Cassidy	Date 12/10/2021