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

27 August 2021

Present:

Name	Capacity	Items
Ms Clare Sanderson	Alternate Vice-Chair	1a, 1b
Dr Martin Andrew	CAG Member	1a
Dr Malcolm Booth	CAG Member	1b
Dr Rachel Knowles	CAG Member	1a, 1b

Also in attendance:

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

1. New Precedent Set Review Applications – Research

a. 21/CAG/0111 – Barts Cancer Research Tissue Bank (CTB)

Context

Purpose of application

This application from Barts Cancer Institute, Queen Mary University of London set out the purpose of medical research that aims to provide support for Barts Cancer Research Tissue Bank (CTB) team staff, who are not members of the direct care team to identify and screen patients attending clinics and wards at Barts Health for eligibility, in order to subsequently seek their consent into the Barts CTB. The aim of the CTB is to recruit patients and healthy volunteers, to collect, store and share high quality tissue and bodily fluids and associated clinical data for research into distinct types of cancer; however, all other processes of the CTB do not require Regulation 5 support, as all participants are consented. The current CTB model is for the direct care team to identify and consent eligible patients, but the applicants have identified that this model is not practicable as the process is very inefficient. The direct care team is not able to spend time identifying and introducing the patients to the CTB team during very busy clinic hours and consequently the number of identified patients is currently very low.

Currently, there is no reliable biomarker for cancer spread in general or for organ-specific identification. The search for a reliable biomarker requires access to uniformly collected, reliably stored, and clinically annotated samples to develop a diagnostic test. This bio-bank will therefore be critical to develop and validate novel cancer metastases biomarkers. These biomarkers will help to reduce the overall health burden by early diagnosis, thus prolonging life through more timely interventions to control disease progression.

Members of the CTB team, who are not members of the direct care team, will use Barts Health patient records such as Cerner Millennium Powerchart, NHS.net calendars and EPR to identify and screen patients that may be appropriate to approach for consent. Any patient who has opted out via the national data opt out will be removed from the screening process. This process is still in development but will be implemented by September 2021. All patients that may be eligible for CTB (e.g. with a suspected or diagnosed gastro-intestinal or other cancer) will be recorded on the shared calendar of the BCI (Barts Cancer Institute) Tissue Bank shared NHS.net email address (within the Barts health NHS Trusts servers). In order to undertake screening, CTB staff will view confidential patient information (Full name, NHS Number, Hospital number, Date of birth). CTB staff will record if a patient is eligible or not on a shared calendar of an NHS.net email address on the Barts NHS Trust servers, using the stated items of confidential patient information. This will show whether a patient needs to be approached to request consent.

The CTB team member will use the shared calendar entries to approach the direct care team and ask whether it is appropriate to approach the identified patient for consent. Providing the direct care team are happy that it is appropriate to consent the patient for research purposes the CTB team member will approach potential patients in order to gain consent. Patient consent or dissent to the Tissue Bank will continue to be recorded on the patient's record on Millennium Powerchart to prevent a dissented patient being inadvertently re-approached. However, the identifiable details of any patient that dissents will not be recorded or stored in the CTB systems. Any hard copies of screening will be destroyed through confidential waste or shredded, although the applicant has confirmed there should not be any paper copies.

A recommendation for class 1, 3 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	All patients attending the surgical, gastroenterology and oncology clinics and wards at Barts Health NHS Trust with a suspected or confirmed malignancy. Approximately 200 patients a week will be screened, to identify approximately 30-40 eligible patients.
Data sources	Barts Health NHS trust: Electronic Patients Record (EPR) and Care Record Service (CRS)/Millennium Powerchart, WinPath, CyberLab and Varian prescribing system, Surginet and surgical diaries. This includes lists of patients attending day-unit, clinics or wards, or theatre lists, which could be provided by direct care team, as well as the physical procedure diary on the day-unit, and NHS.net calendars.
Identifiers required for identification of cohort	1. Full name 2. NHS Number 3. Hospital number 4. Date of birth
Identifiers required for analysis purposes	1. N/A – undertaken with consent

Confidentiality Advisory Group advice

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

Public interest

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

The members agreed that there is a medical purpose and strong public interest in the development of markers for metastases and pancreatic cancer particularly.

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 are intending to seek consent at the earliest opportunity, however, it is not possible to identify and screen for eligibility with consent. The Sub-Committee were content with the justification provided.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for the identification of the correct patients, and screening of the patient for eligibility. Data is collected with consent at the earliest opportunity, however, it is not possible to identify and screen for eligibility using anonymised information. The Sub-Committee were content that this could not be undertaken in any other 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 applicant has confirmed that to highlight the pre-screen process for patients, a statement will be included within the clinical appointment letter and also on the CTB website. This is in line with previously supported applications.

The national data opt out will be applied, and a study specific opt out is offered for the screening, sent out on clinic letters and on website. This is also in line with previously supported applications.

The Sub-Committee voiced concern over the surprisingly common scenario of patients not realising before they see the clinician that they are being investigated for cancer, however, they noted that a good feature of the application is that the tissue bank team will discuss the suitability of the patient with the clinician before approaching the patient, which would remove this possibility. The CAG therefore strongly encourage the tissue bank team to discuss the suitability of the patient with the clinician before approaching the patient, as described in the application, so they can be mindful of how the approach may be received.

Related to the above point, the members felt that the wording in the clinical appointment letter would benefit from a statement that not all patients being invited (to the clinic appointment) will turn out to have cancer, so that patients do not interpret this as someone has decided they have cancer before being seen by the clinician. However, it is noted that the notification statement provided to CAG is an addendum to the clinical appointment letter and not the entirety of the letter the patients will receive, and the letter is additionally not sent for research purposes. The applicant is therefore requested to confirm if there are words to this effect as part of the text of the rest of the clinic letter.

The Members were content with the opt out options provided, however, they wished for the applicant to make a small amendment regarding the ordering of the opt out options on the patient notification/website text. The CAG also felt that it should be made clear that the national data opt out would opt out the patient out of all research and the local opt out is specific for data access for processing pre-consent on this project only, and therefore the options should be offered in an alternative order, with an additional description, to ensure patients understood the implications regarding using the national data opt out.

The opt out currently reads; '*Should you not want your data to be accessed for this purpose, you can either go to https://digital.nhs.uk/services/national-data-opt-out, or alternatively, you can opt out **of this specific research project** locally by contacting tissuebank-bci.bartshealth@nhs.net or 020 7882 8815 or visit https://www.bartscancer.london/core-services/tissue-banks/* '

Please consider changing this section to; '*Should you not want your data to be accessed for this purpose, you can opt out **of this specific research project** locally by contacting tissuebank-bci.bartshealth@nhs.net or 020 7882 8815 or visit https://www.bartscancer.london/core-services/tissue-banks/;* If you wish to opt out from the use of your data for all research or planning purposes you can opt out via https://digital.nhs.uk/services/national-data-opt-out'.

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.

Twenty patients attending oncology clinics have been consulted on their views on accessing identifiable data prior to consent. CTB delegated staff explained that the information will be only used to identify eligible patients for tissue donation and that the information is only used by authorised CTB staff. There was general acceptance (100% of 20 patients) that processing of identifiable patient data without consent was acceptable for the purposes described in this application.

The Sub-Committee were content that although the Patient and Public Involvement was not very detailed, it is adequate for the requirements of this application.

Exit strategy

Once consent is obtained, 'Section 251' support under the Regulations is no longer required. Where consent is not obtained, the identifiable data is deleted. A note remains on the patients electronic medical records to show they have declined the CTB, and support is not required for this element. However, as applicants are continuously screening, ongoing support for the process is required. Applicants are applying for 5 years ethics renewal, CAG support requested for 5 years in line with REC. The Members were content with this exit strategy.

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. Support provided for 5 years in the first instance. A duration amendment will be required at this time to extend support.

2. Please confirm if the clinical appointment letter makes clear that not everybody invited to clinic will turn out to have cancer, within one month from the date of this letter.

3. Please amend the order and description of the opt out options as described above, and provide an updated version to CAG, within one month from the date of this letter.

4. Favourable opinion from a Research Ethics Committee. **Confirmed 09 December 2019**

5. 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 **20/21** DSPT review for **Barts Health NHS Trust** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 21 September 2021)

b. 21/CAG/0114 - Trends in the Prevalence and Complexity of Children with a Life-limiting or Life-threatening condition in Wales

Context

Purpose of application

This application from University of York set out the purpose of medical research that aims to estimate the number of children in Wales who are living with a Life-limiting or Life-threatening condition (LLC) and to assess the complexity and severity of this population to aid service planning and delivery. The applicant proposes to use Digital Health & Care Wales (DHCW) (Formerly known as NHS Wales Informatics Service NWIS) as a trusted third party to undertake linkage with Welsh clinical data from Secure Anonymised Information Linkage (SAIL) databank, Paediatric Intensive CareAudit Network (PICANet) data, and data from NHS Digital.

Life-limiting conditions (LLC) are serious health conditions in which the child's life may be shortened. Children living with an LLC usually have repeated admissions to hospitals and require healthcare including palliative care for many years. A challenge in LLC research is lack of information on the severity or complexity of the child's condition. This application will link data from different sources which will be pivotal for service planning and provision.

Identifiable data from NHS Digital and PICANet from all Wales residents ageing 0 to 25 years old is sent to DHCW to be linked and for cohort identification. The data linkage will be undertaken by the SAIL Databank team and DHCW. Data for any individuals who do not meet the cohort inclusion criteria will be deleted once the cohort has been made. After linkage, data will be pseudonymised using a unique identifier that matches with SAIL datasets. This dataset will be disclosed to SAIL, alongside full date of death for those who have passed away. SAIL will then link to clinical data and modify date of death to month and year of death 6-8 weeks after receiving the dataset. 's251' support will then no longer be required. Researchers from the University of York will have access to the pseudonymised dataset via secure remote access provided by SAIL.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	All children and young adults aged 0-25 years old with a life-limiting condition (LLC), resident in Wales from 2003-2020. ~63,000 cases
Data sources	1. SAIL databank (linked via Digital Health & Care Wales (DHCW) (Formerly known as NHS Wales Informatics Service, (NWIS); • Primary Care GP (2000-2020) • Patient Episode Database for Wales (PEDW) (1997-2020) • Critical Care Dataset (2006-2020) • Emergency Department Data Set (EDDS) (2009-Present) • Outpatient (2004-2020) • Annual District Death Extract (2003-Present) • Congenital Anomaly Register and Information Service (CARIS) (1998-2019) • Welsh Cancer Intelligence and Surveillance Unit (WCISU) (1972-Present) 1. The Paediatric Intensive Care Audit Network (PICANet) data from the University of Leeds 2. NHS Digital; • Hospital Episode Statistics (HES) (A/E; Admission; Outpatient) • Emergency Care Data Set (ECDS)
Identifiers required for linkage purposes	• NHS Digital linkage: 1. NHS Number 2. Postcode 3. Date of birth 4. Sex • PICANet linkage: 1. PICANetidentifier 2. Name 3. NHS number 4. Postcode 5. Date of birth 6. Sex
Identifiers required for analysis purposes	1. Date of death (modified to month and year) 2. Ethnicity
Additional information	Data linkage undertaken by Digital Health & Care Wales (DHCW) The pseudonymised dataset will be hosted by the Secure Anonymised Information Linkage (SAIL) databank at Swansea University. The researchers at the University will access and analyse the dataset via secure remote access provided by SAIL.

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 an appropriate medical purpose and is in the public interest.

Practicable alternatives

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

- **Feasibility of consent**

The applicant has reasoned that consent would not be feasible as the cohort includes a large number of people. Also, some of the cohort will be deceased, and it is not possible to get consent from these patients. The Sub-Committee accepted the justification provided and agreed that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage, and it would not be possible to undertake this with anonymous or pseudonymous data. The Sub-Committee agreed with this could not be undertaken in a 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.

There will be information about this study on the Martin House Research Centre Website (University of York), SAIL website and the Welsh government Palliative care website - https://wales.pallcare.info/. The website text has been provided.

The applicant has explained that they are not offering a study specific opt out due to DHCW not having sufficient staff and resources, however one seems to be offered on the notification document. The opt out option on the notification text also asks the person to contact SAIL,

however it is understood that this would not work as an opt out option, as SAIL would not be able to identify the individual from the data held. Participants are also asked to opt out via the national data opt out. The national data opt out and PICANet opt out will be respected.

The Members did have some reservations about the proposed lack of a study-specific opt out. The application form states it is 'difficult to implement' and the answers to Confidentiality Advice Team (CAT) queries states that DHCW (previously NWIS) does not have sufficient staff and resources. It is not clear if this means DHCW will never be able to implement an opt out or that there are currently special circumstances. The Sub-committee appreciate that implementing an opt out may be beyond the control of the researchers, and would accept no study specific opt out if that is the only option, however they requested a further explanation.

The CAG considered that the website text regarding opt out options was not clear about what would happen if a parent contacted the research team, especially as the applicant has stated dissent cannot be implemented by them. The Members would prefer that the text stated to contact the research team to find out more about the study rather than to opt out, if opt out is not a possibility, as it currently seems misleading. There are also no contact details for the research team provided on the website notification.

The final section of the website text should therefore be amended to state that parents can contact the research team to find out more about the study, and contact details should be provided. References to contacting SAIL should be removed. If after further explanation, it is impossible for DHCW to implement a study specific opt out option, the website notification should make it clear that parents will have to use the national data opt out if they wish to object, noting CAG would not generally advise applicants to encourage people to use the national data opt out as a way to opt out of one specific study.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public are 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.

An independent Study Steering Committee (SSC) of 5-6 individuals will be chaired by a representative of the Wales Paediatric Palliative Care group. This group will also contain a patient and public representative. Patient, Public and Stakeholder Engagement is integrated throughout the project via the Martin House Research Centre Family Advisory Board (FAB) and input through the study. This study was presented to the FAB members of the Martin House Research Centre (www.york.ac.uk/mhrc) on the 1st March 2021. 7 parents were present - all their children have very complex health conditions - two of the parents their children had died. The parents were supportive of the research and stated they wished that data were shared to inform the care of their children. The FAB group were supportive as the data that would be analysed would not be identifiable and that the appropriate safeguards were in place. One parent raised an issue of whether this would set a precedent for wider use of data without consent - she felt using patient identifiable data without the parent's consent was appropriate for this study. The FAB group will be consulted with the findings and will help develop a Plain English Summary at the end of the study.

Exit strategy

All confidential patient information will be deleted immediately after data linkage is performed by DHCW, except the date of death which will be sent to SAIL. SAIL will modify this to month and year of death approximately 6-8 weeks after receiving it. The applicant is unsure when this

will be completed, as it depends when the data is available, but it could be in 2022. 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 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 provided further explanation as to why it is not possible for DHCW to implement a study specific opt out.

2. The website notification should be amended and an updated version provided;
   a) It should be clarified that parents can contact the research team to find out more about the study (not to opt out),
   b) Contact details for the research team should be provided.
   c) References to contacting SAIL regarding opt out should be removed.
   d) If after further explanation, it is impossible for DHCW to implement a study specific opt out option, the website notification should make it clear that parents will have to use the national data opt out if they wish to object.

3. Please provide evidence of NHS Digital review of the 20/21 DSPT for PICANet – University of Leeds SEED, and Secure Anonymised Information Linkage (SAIL databank), as per standard condition of support below.

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

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

1. Favourable opinion from a Research Ethics Committee. **Confirmed 11 August 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 **20/21** DSPT reviews for **NHS Digital and PICANet – University of Leeds LASER** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 14 September 2021).

   However the NHS Digital **20/21** DSPT reviews for **PICANet – University of Leeds SEED (it is not clear if PICANet have moved from SEED to LASER at this time), and Secure Anonymised Information Linkage (SAIL databank) 8WG95** were **pending.**

   Digital Health & Care Wales (DHCW) has a confirmed Caldicott Principles into Practice (CPiP) Outturn report.

Minutes signed off as accurate by correspondence from Ms Clare Sanderson, CAG Alternate Vice-Chair		*04 October 2021*
Signed – Officers of CAG		Date
Caroline Watchurst		01 October 2021
Signed – Confidentiality Advice Team		Date