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

24 September 2021

Present:

Name	Capacity	Items
Dr Patrick Coyle	CAG Vice-Chair	1a, 1b, 1c
Professor Lorna Fraser	CAG Member	1a
Dr Katie Harron	CAG Member	1a, 1b, 1c
Professor Jennifer Kurinczuk	CAG Member	1b, 1c

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor
Ms Caroline Watchurst	Confidentiality Advisor
Mr Michael Pate	Confidentiality Advisor

1. New Precedent Set Review Applications – Research

a. 21/CAG/0131- Confirming ongoing nasogastric tube position – an analysis of practice and outcomes between the UK and Australia

Context

Purpose of application

This application from the University College London Hospital NHS Foundation Trust (UCLH), in partnership with Queensland University of Technology (QUT), set out the purpose of medical research that seeks to conduct a prospective observational chart review on hospitalised adults with Naso-Gastric Tubes (NGTs) from one Trust in the UK, to measure outcomes associated with ongoing confirmation of NGT position using pH testing. Anonymous results will then be compared with an Australian cohort to determine the difference between outcomes.

The literature to support any method of ongoing testing of NGT position is limited and of poor quality. Primary evidence is required to assess the risks and benefits of any of the available options. However, Trusts and national policies set standards for safe practice in this area, despite the lack of available evidence. Therefore, this research aims to contribute to the evidence in the field to guide policy and practice to improve patient outcomes.

A feasibility study was successfully completed in May 2021. This demonstrated it was possible to extract meaningful data from patients' electronic medical records (without patient contact or consent) to address the study objectives. The method of data extraction has proven valuable during COVID as patients and clinicians do not have any additional patient contact for research purposes. As the study protocol now includes more patients and wards required to perform a fully powered study, the data collection will not all be conducted by a dietitian already involved in the patients care. Therefore the applicant requires ‘s251’ support to cover the extraction of a pseudonymised dataset for analysis by somebody who is not considered direct care team.

The ward dietitians (direct care team) will send a list of new NGT patients, to the data collector and primary researcher via secure chat in the UCLH electronic notes system. Once the patient has been included in the study, UCLH requires that patients are marked as enrolled in the study, within EPIC. Support is not required for this marker as it is within the Trust systems. Initials and identifying information regarding ward and bed number are deleted from the collected dataset post data collection. The final dataset which can be considered anonymous to the recipients, is transferred to Queensland University of Technology for analysis.

A recommendation for class 1, 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	120 adult inpatients requiring nasogastric tube feeding (in UCLH only)
Data sources	1. University College London Hospital NHS Foundation Trust; EPIC electronic patient records
Identifiers required for data collection/extraction purposes	1. Patient initials 2. Patient location (Ward) 3. Patient bed number 4. Patient ID (made up of the above 3 data items) 5. Electronic Medical records viewed in order to extract dataset
Identifiers required for analysis purposes	1. Patient location (Ward) 2. Age in years 3. Gender Can be considered anonymous for disclosure to Australia
Additional information	Prospective Observational Chart Review - Data will be collected daily, 24 hours in arrears, by the primary researcher (or the allocated dietitian at UCLH) using the UCLH remote working access

Confidentiality Advisory Group advice

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

Public interest

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

The Sub-Committee agreed this study has a clear 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 reasons that patient informed consent is not possible to obtain without a high risk of that information causing material changes to current normal practice in obtaining pH results from NGTs, as nursing staff would be aware of the research. This is evidenced by a discussion with nursing staff - the nurses suspected that knowing they were being observed could change both their and their colleagues' practice, and therefore supported that this research should be conducted without full disclosure to nursing staff. The design of data collection without consent is backed up by patient and public involvement undertaken with patients. The CAG accepted these justifications and agreed that consent was not a practicable alternative.

- Use of anonymised/pseudonymised data

Confidential patient information is required to identify eligible patients and extract a dataset for analysis. It is not possible to extract the specified data from medical records without processing confidential patient information. The CAG agreed the applicant has minimised the use of confidential patient information as far as possible.

'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 originally provided only a nursing notification poster, and sated that in participating wards posters will be placed in nursing break rooms to inform them the research is being conducted. The applicant has argued that having a patient notification that describes what the study is would change nursing practise, which is the subject studied. However as a response to queries, the applicant has designed a study poster for patients to be put up on wards, and stated they will use this if CAG wish.

A local opt out option is provided on this poster, which is by letting their dietician know. Additionally, in the electronic medical records (EPIC) at UCLH, patients can elect to restrict their records. If the patients' records are restricted then the health care professional is required to "break the glass" before reviewing the records. These patients will be excluded from the research. The National data opt out will be respected.

The Members were unclear why a nursing notification poster was required, given the applicants clear reasoning surrounding not informing nursing staff of the research. However this is a comment only, as the Members did not feel any conditions were required, as it would not influence the CAG decision.

The CAG discussed whether patient notification should be required, given that any patient notification will be seen by nurses, which as the applicants have argued, could change practice. However, the CAG felt that the poster provided by the applicants would let patients know enough about the study without giving too much information to nurses that could change

practice, and therefore agreed that the applicant should use this poster, which then provides an appropriate opt out option.

The Members wished for some amendments to the poster regarding amending incorrect references to CAG 'approval' and the Data Protection Act. The CAG is not a decision-making group and instead provides recommendations to the decision maker, the Health Research Authority in this case. Additionally, CAG remit is regarding the common law duty of confidentiality rather than GDPR. The statement on the poster currently reads; '*This research has been approved by the NHS ethics committee and the NHS Confidentiality Advisory Group, who has reviewed whether this study protocol complies with UK data protection legislation.'*

This statement should be amended to something similar to; '*Surrey Research Ethics Committee has given a favourable opinion of the study. The Health Research Authority, on advice from the Confidentiality Advisory Group (CAG), has supported the use of confidential patient information without consent, under section 251 of the NHS Act 2006'*

The section stating; *'If you have questions about the approval from the Confidentiality Advisory Group, please contact them on cag@hra.nhs.uk*.' should be omitted. Instead, the contact details of the Chief Investigator should be added for any queries about the study.

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.

Ten English-speaking in-patients that currently or recently had an NGT were interviewed by the lead researcher. All patients were happy with dieticians collecting information from the medical notes in the manner described in the application, and all gave the opinion that they would not expect to be asked for consent for this data to be collected. All ten patients had no concerns about sharing fully de-identified results with Australia, without collecting consent, to compare with equivalent results collected there. The Sub-Committee were content with the patient and public involvement undertaken.

Exit Strategy

The pseudo ID will be deleted at the end of the data collection, and no key will be retained. The exit strategy is therefore anonymisation of the dataset, which is undertaken at the end of data collection before disclosing dataset to Australia for analysis. The data collector will be working on data collection full time. There will be an initial 8 weeks during which patients are enrolled into the study. Due to data being collected for up to 14 days after initial enrolment, data will be collected for a total of 10 weeks, after which time, support will no longer be required. The members were content with the proposed 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. The applicant should display the patient notification poster, and this should be altered as per the descriptions above, to include updated references to CAG, and contact details for the Chief Investigator, and remove references to contacting CAG. The updated poster should be provided to CAG within one month from the date of this letter.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 27 July 2021 (for amendment relating to CAG application)**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS Digital **20/21** DSPT review for **University College London Hospital NHS Foundation Trust** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 06 October 2021)

b. 21/CAG/0132 - Evaluating the health inequality effects of the Best Practice Tariff for hip fracture

Context

Purpose of application

This application from the University of York (UoY) set out the purpose of medical research that seeks to explore whether the introduction of the best practice tariff (BPT) for fragility hip fracture in 2010 and subsequent changes to its components in 2017 led to changes in health inequalities across the population of England. This is a retrospective, observational study, which proposes to link clinical information which is already collected as part of the National Hip Fracture Audit database (NHFD) with Hospital Episode Statistics (HES) data and Office for National Statistics (ONS) Mortality data, using NHS Digital as a trusted third party to create the bridging file. 's251' support is required to undertake linkage between the datasets.

A hip fracture is a serious injury that carries a risk of death and long-term pain. It is possible that the introduction of the hip fracture BPT might lead to improvements in care delivery that benefit predominantly those with higher socioeconomic status, thereby widening inequalities. Applicants will compare how care changed in Wales over time to how care changed in England

over time to tell us what difference BPTs made to each socioeconomic group of people. Applicants will then be able to describe the impact of BPTs on quality and length of life across the whole population.

In order to undertake this linkage, Crown Informatics, who process the NHFD data on behalf of Royal College of Physicians (RCP), will transfer confidential patient information to NHS Digital, (as the data controller for HES and ONS mortality data) to generate a bridging file containing NHFD ID and HES ID which is then disclosed to the applicants at UoY. Crown informatics will also disclose a clinical dataset containing NHFD ID to the applicant at UoY. The Centre for Health Economics at UoY already holds linked HES+ONS data that are used for a number of research projects, which contains HES ID, and also contains full date of death. NHFD and HES+ONS data will be linked by a member of the research team, using the bridging file, after which, the bridging file and the HES ID / NHFD ID in the resulting dataset will be deleted. Dates of events will be used to calculate time interval in days between events, so that the final analysis dataset will not include any dates. This will be effectively anonymous for analysis.

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

Confidential patient information requested

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

Cohort	Approximately 600,000 hip fracture patients in England and Wales during the period 01 April 2008 to 31 March 2020 All individuals included in the National Hip Fracture Database will be included.
Data sources	2. Crown Informatics (on behalf of the Royal College of Physicians, commissioned by HQIP); National hip fracture audit database. 3. NHS Digital – controller for Hospital Episode Statistics (HES) data and Office for National Statistics (ONS) mortality datasets, however the Centre for Health Economics at University of York already holds HES+ONS data, and outcomes will be sourced from this dataset (provided to UoY under DARS-NIC-84254-J2G1Q).
Identifiers required for linkage purposes	Disclosed from NHFD to NHS Digital: 1. NHS number 2. Date of Birth 3. Postcode 4. Sex 5. NHFD ID Bridging file disclosed from NHS Digital to University of York: 1. NHFD ID

	2. HES ID (not possible for applicants to re-identify patients)
Identifiers required for analysis purposes	1. LSOA (provided by Crown informatics) 2. Sex 3. Date of death – modified to survival time from admission (in days). Effectively anonymous to applicants
Additional information	HES & ONS outcome data will be extracted for all included patients up until up to 31st March 2020.

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 this project has a medical purpose which 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 reasons that as this is a retrospective study of over 600,000 individuals with a hip fracture between 2008 and 2020, some of these patients would have died since having their hip fracture care; and others would have moved or are otherwise lost to follow-up. The NHFD does not track individuals over time and therefore does not hold information on current addresses. The University of York will also not have access to the names and addresses of these patients and therefore would require additional disclosures if they were to seek consent form patients directly. Additionally 600,000 patients would be a logistically very difficult task which would make consent not a practicable alternative. The CAG agreed that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to undertake linkage. The Sub-Committee did not think using anonymous or pseudonymous information was a practicable alternative, and the applicant appears ot have minimised the use of identifying information as far as possible.

‘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 provided an updated privacy notice and a notification in response to Confidentiality Advice Team (CAT) queries. These will be posted as a news item and as a webpage on the CHE (UoY) website, and will be reviewed by a patient and public involvement member but this has not yet been undertaken. Applicants have enquired with RCP as to whether the news item and link to the notification can be shared on the respective RCP and/or NHFD webpages.

University of York cannot themselves record or apply individuals' dissent from the use of their records for the purposes of this application, as they do not hold any identifiable information. The applicant has reasoned that individuals who wish to opt out will have to register their opt-out via the national data opt-out or by contacting NHFD to record their dissent (https://www.rcplondon.ac.uk/projects/outputs/fffap-data-processing-statements). However this would opt a person out of all uses of their data, or the entire hip fracture audit respectively. The applicant has stated that RCP have not managed to implement study specific opt outs previously, and therefore this will likely not be possible for this project. The NHFD opt out will be respected. The National data opt out will be applied by NHS Digital.

The Members considered the language of the patient notification could be simplified, and wondered if the general public would understand phrases such as "*health inequity impact*" or what is meant by "*bridging file*". The members also noted that there is a line in the patient notification document that needs to be edited, as it currently reads *"The aim of this research is see whether the was hospitals are paid for the hip fracture care they provide".* The applicant is therefore required to simplify the language of the notification, and ensure accuracy. It is noted that the applicant states patient and public involvement representatives have not yet looked at the notification document, and this review could help with ensuring lay language is used.

The CAG accepted that study specific opt-out appears not possible in these circumstances, as the data controllers of the NHFD do not have methodology in place to facilitate this.

Patient and Public Involvement and Engagement

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

The applicant has recruited members of the public rather than users of specific services. Three members of the public were involved in the design of the overall research proposal. Members of the public will advise on interpretation and dissemination once the analysis is complete. As a response to CAT queries regarding whether the use of confidential patient information without

consent was acceptable to patient and public representatives of the cohort, it is not clear that this point has been considered or discussed.

The CAG considered that the patient and public involvement undertaken is very limited, with only three people taking part, who seem to have advised on a much larger umbrella project. The Sub-Committee did not consider three opinions to be proportionate to the breach being undertaken, considering the dataset is 600,000. The CAG request that the applicant undertake more patient and public involvement, with a larger number of patients, which is more specifically focused on the use of confidential patient information without consent. It is felt that this is particularly important because there currently isn't a clear way of opting out. Despite the applicant analysing an effectively anonymous dataset, the confidential patient information of 600,000 patients is processed in order for the linkage to be undertaken. This breach of confidentiality should be in the public interest, and patient and public involvement is one way that CAG identify if an activity should be undertaken.

Exit Strategy

NHS Digital will destroy any confidential patient information received once a bridging file has been generated. Applicants estimate this will this be completed 12-16 weeks after receipt of the cohort from Crown Informatics. UoY will destroy the bridging file and remove the HES ID / NHFD ID in the resulting dataset after undertaking linkage within 20 working days of full data receipt. UoY will modify and delete date of death within 20 working days of full data receipt. The Cag 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 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 simplify the language of the patient notification, and ensure accuracy. Please ensure this is reviewed by a patient and public involvement group, rather than one individual, and provide the updated notification to the CAG.

2. Please undertake more patient and public involvement, with a larger number of patients, which is specifically focused on the use of confidential patient information without consent.

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, a final support outcome will be issued.

Specific conditions of support (provisional)

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

1. Favourable opinion from a Research Ethics Committee. **Confirmed 29 July 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. **Confirmed:** The NHS Digital **20/21** DSPT reviews **for Crown informatics, NHS Digital and University of York EE133913-CHE** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 12 October 2021)

c. 21/CAG/0135 - Clinical management of Patients with Malignant Bowel Obstruction: A Multi-centre retrospective Cohort Study

Context

Purpose of application

This application from the University of Hull set out the purpose of medical research that seeks to describe the presentation, management and outcomes of those admitted to hospital with Malignant Bowel Obstruction and identify predictors of better outcomes.

Malignant Bowel Obstruction (MBO) is a common, distressing complication of bowel, gynaecological and other cancers. It causes severe pain, intractable nausea and vomiting, anorexia and death. It has a profound effect on patients' quality of life and involves repeated and prolonged hospitalisation for persistent and unresolved symptoms. Numerous management options are possible, from surgery or stenting to less invasive approaches such as medication or tube-drainage of intestinal contents. Each patient's situation is unique, making clinical decision-making difficult. Surgery gives the best option for longer-term survival in the "right" patients, but there are currently no nationally agreed guidelines and practice varies widely nationally. Non-surgical palliative approaches for inoperable MBO (IMBO) usually involve administration of a combination of parenteral antiemetics and anti-secretory agents, yet

the evidence is inconclusive regarding their effectiveness. Tailored treatments may benefit individuals, but there is little guidance to support clinicians and patients in decision-making. Two other therapeutic options for the management of MBO are available; venting gastrostomy (VG) and parenteral (intravenous) nutrition (PN). Limited evidence is available regarding their use or to inform clinical decision making.

The applicants will undertake a historical cohort study of patients who were admitted to two hospitals, Hull University Teaching Hospital NHS Trust and Leeds Teaching Hospitals NHS Trust. Patients with a diagnosis of malignant bowel obstruction will be identified via hospital coding by business intelligence teams at the two trusts. Patients will then be followed from the time of those records to the present day or the patient's death. The research team will then access patient records in order to extract an anonymised dataset.

A recommendation for class 1, 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	Patients aged 18 years and over, diagnosed with cancer and bowel obstruction, who were admitted to Hull University Teaching Hospital NHS Trust and Leeds Teaching Hospitals NHS Trust between 01 January 2019 to 31 December 2020. The applicants anticipate that 350 patients will be recruited.
Data sources	4. Electronic and paper patient records at Hull University Teaching Hospital NHS Trust and Leeds Teaching Hospitals NHS Trust
Identifiers required for linkage purposes	6. Hospital ID number
Identifiers required for analysis purposes	4. Gender 5. Ethnicity
Additional information	The applicants will be provided with patient's hospital number by the Business Intelligence team, so that the applicants can access paper and electronic records.

Confidentiality Advisory Group advice

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

Public interest

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

Scope

The CAG requested confirmation that the Business Intelligence Teams have a right to access confidential patient information as part of their usual work. The applicants confirmed that this was the case and clarified that the Business Intelligence Team will not access patient medical records. They will be searching for patients who have been coded as having bowel obstruction and a diagnosis of cancer. They will then provide a list of names and NHS numbers to the researchers, who will then check the medical records. The CAG raised no further queries in this area.

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 explained that it is not feasible to seek consent from deceased patients. For living patients, the applicants advised that seeking consent, or a consultee opinion if patients lacked capacity, may mean that recruitment is limited to those both eligible and willing to participate, or who have a consultee. This may introduce volunteer bias.

- Use of anonymised/pseudonymised data

The research team require access to confidential patient information in order to extract an anonymised dataset for analysis.

'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 advised that a link will be placed on the Research and Development sections of Hull University Teaching Hospital NHS Trust and Leeds Teaching Hospitals NHS Trust websites. This will direct patients to the study, including an option for participants to dissent from the use of their records. Any patients who dissent will be withdrawn from the study.

The applicant provided the texts to be displayed on the R&D website and the study website. This provided information on how patients can dissent and telephone, email and postal contacts to register dissent.

The research team will check patients' medical records (paper and/or electronic) for evidence of existing dissent prior to any data collection. The National Data Opt-out will be applied.

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.

Four members of the Involve Hull Patient and Public Involvement (PPI) group, who have experience of cancer themselves or in supporting others with cancer, were involved in the research design, the undertaking of the research and the dissemination of the research findings. Four topics were discussed, including the use of medical notes without consent. In the initial discussion around accessing confidential patient information without consent, the opinions of the group were divided on whether this was ethical or not. The group was then given further information on the process of extracting anonymised data and details about the HRA Confidentiality Advisory Group. Following further discussion, the PPI representatives were happy to support the use of confidential patient information, as long as the data was anonymised as planned.

The PPI group agreed to provide contact details so that they could be involved in an advisory group, which would meet prior to each TAP. During these meetings, the researchers will give a report on the research progress and the group will be asked for their insights into the research findings.

The PPI group will also be involved in the development of public-facing research outputs and the decisions around the next steps in the research cycle.

The applicants provided the information sheet (Cancers that cause bowel obstruction information sheet) which was sent to all PPI participants before the meeting. This outlined the research purpose and design. The Flyer used to recruit PPI participants (Michael Patterson PPI Flyer) was also provided. The PPI Group was asked to comment on accessing medical records without prior permission from the individual. The PPI participants were in favour of the project, if reassurance that data will be anonymised, and only relevant data will be abstracted, was provided. The reasons for wanting to access these data were agreed as good and likely to bring benefits to people affected by this condition and the PPI Group felt this outweighed the consent issue. The PPI Group was uncomfortable with the thought of approaching relatives of the deceased because they might not want to talk about this, and it might cause distress.

Exit strategy

The dataset will be anonymised at the point of extraction. The CAG raised no queries in this area.

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. Favourable opinion from a Research Ethics Committee. **Confirmed 05 October 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. **Confirmed:**

   The NHS Digital **2020/21** DSPT review for **Hull University Teaching Hospitals NHS Trist and Leeds Teaching Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 08 October 2021).

Minutes signed off as accurate by correspondence from Dr Patrick Coyle, CAG Vice-Chair		05/11/2021
Signed – Officers of CAG		Date
Caroline Watchurst		21/10/2021
Signed – Confidentiality Advice Team		Date