Minutes of the meeting of the Confidentiality Advisory Group

15 August 2019 at HRA Manchester, Barlow House

Present:

Name	Present	Notes
Ms Sophie Brannan	Yes	Lay Member
Dr Malcolm Booth	Yes	
Dr Patrick Coyle	Yes	Vice Chair
Mr Myer Glickman	Yes	
Mr Anthony Kane	Yes	
Dr Rachel Knowles	Yes	
Mrs Diana Robbins	Yes	Lay Member
Dr Murat Soncul	Yes	
Ms Gillian Wells	Yes	Lay Member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Miss Kathryn Murray – by telephone	Senior Confidentiality Advisor

1. Introduction, apologies and declarations of interest

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care has not yet provided a response to the advice provided by the CAG in relation to the **04 July 2019** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **04 July 2019** meeting applications.

3. Resubmitted Applications – Non-Research

a. 19/CAG/0145 (previously CR9/2014) Transfusion Medicine Epidemiology Review

Context

Purpose of application

This application from the University of Edinburgh set out the non-research purpose of a public health surveillance review to determine whether Creutzfeldt–Jakob is transmissible through blood transfusion. This application has existing support under application reference CR9/2014.

Transmission of CJD via blood transfusion is an important public health issue, particularly since the advent of variant CJD (vCJD). Three cases of vCJD and one sub-clinical infection have been linked to transfusion transmissions through this study so far.

The refreshed application set out the request for revisions to the scope of support which is in place for the activity. Previously, identifiers from all individuals with definite or probable variant CJD eligible to donate blood were notified to the four blood services within the UK to check whether the individual had donated. For other forms of CJD, identifiers were only forwarded from those with a history of blood donation reported by a surrogate witness. This information cannot be directly collected from the patient due to the nature of their illness. The revised protocol standardises the procedure for other forms of CJD to that which is in place for vCJD, so that the blood services are notified of all cases of other forms of CJD. This change is being made as an audit of the accuracy of the history of blood donation found that not all patients who had donated blood were reported as doing so by a surrogate witness. There were potential public health implications in not identifying all cases of patients with CJD who also donated blood.

The NCJDRSU will also ascertain whether any of the identified donors or recipients were known to have died from CJD. If so, data from the NCJDRSU unit on cases of CJD/vCJD will be linked to data from the national blood services who provide details of recipients/donors to these CJD/vCJD cases. Details of these recipients/donors are then sent to NHS Digital for flagging.

Support was also sought to enable review of the medical records of any flagged donors or recipients who had 'dementia' listed as a cause of death on their death certificate, in order to identify those who may have died from CJD or vCJD but were not diagnosed in life. The death certificates will be obtained via NHS Digital, and the Hospital and GP records will be requested via the medical records departments of the hospitals or primary care providers. Copies of the records will be requested and an NCJDRSU clinician will review the records to establish whether the patient could have been suffering from CJD/vCJD according to the established diagnostic criteria for CJD. The notes will then be destroyed.

Data from the NCJDRSU unit on cases of CJD/vCJD is linked to data from the national blood services who provide details of recipients/donors to these CJD/vCJD cases. Details of these recipients/donors are sent to NHS Digital for flagging. This flagging exercise was previously undertaken with the then HSCIC under the class action application.

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	Individuals included in this cohort are: a) people who have received blood components from donors who were later identified as suffering from CJD/vCJD, b) people whose donated blood components were transfused to persons later identified as suffering from CJD/vCJD. Patients have been recruited from 1997 onwards, and recruitment is ongoing. No new cases of vCJD have been identified since 2016. 392 recipients and 745 donors have been recruited so far.
Data sources	1. The National Blood and Transplant Service 2. The Welsh Blood Service 3. NHS Digital 4. GP records 5. Hospital records
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Sex 4. Address and postcode at time of blood donation and transfusion 5. Cause of death 6. Date of death
Identifiers required for analysis purposes	1. Name 2. Date of birth 3. Sex 4. Address and postcode at time of blood donation and transfusion 5. Cause of death 6. Date of death 7. Type of blood component transfused (red cells, platelets, etc) 8. Date blood component donated

	9. Date of transfusion 10. Hospital number 11. Name of hospital where transfusion took place 12. Summary reason for transfusion
Additional information	

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.

The Group recognised the clear public interest in the project.

Scope

The Group noted that a number of activities were undertaken during the project. It was not clear which activities involved the sharing of confidential patient information without consent. The data flows needed to be clarified, and each activity that required support should be specified, in order to clearly describe the scope of support required for the application activity.

The application referred to data linkage with NHS Digital. NHS Digital only handle data generated within England, and the CAG queried whether the data for patients in Wales would be linked to corresponding records held by NHS Wales Informatics Service. Members agreed that the applicant would be asked to provide a clear overview of all data flows involved in the proposal, identifying which flows fell within the scope of support under the Regulations. A revised data flow diagram would also be requested to support this response.

<u>Practicable alternatives</u>

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 explained that the data collection was retrospective and did not involve patient contact or analysis of stored blood samples.

The majority of patients recruited for this application were deceased at the time of flagging, therefore consent could not be sought. The applicants explained that contacting living recipients or the relatives of deceased recipients would cause unnecessary distress.

The Group recognised the difficulties in seeking consent from the two cohorts involved. Consent could not be sought prospectively from those receiving transfusions, due to the usually emergency nature of transfusions.

The Group considered whether consent could be sought prospectively from blood donors when making their first donation. When consenting to give blood, donors were asked to consent to the use of their blood and data for purposes other than donation to others. Members noted that a considerable amount of time may pass between the consent being taken and the data being accessed by the applicants, if at all, and so the consent may be considered out of date. The Group also noted that over a million units of blood are donated each year, and that consenting all donors would be unfeasible.

The Group remained assured that consent was not feasible for the proposal.

- Use of anonymised/pseudonymised data

Confidential patient information was required to flag specific individuals who meet the criteria for inclusion in the review. Information on individual cases of CJD will be held on the NCJDRSU database to be linked with current and archived datasets held by the four Blood Services within the UK and UK hospital blood banks. There was no common identifier that can be used to link information across these sources.

The applicants explained that, as information on transfusion and donation were obtained from the relatives of patients with CJD in the first instance, the information may be incomplete or inaccurate, therefore linkage to the UK Blood Services was required.

The Group accepted the applicant's rationale for using confidential patient information.

Health related feedback given to patients

Individuals who had received a blood transfusion from an individual who later developed CJD would be unaware that this had happened. The applicants explained that the issue of informing patients who had received contaminated blood had been considered by the research ethics committee that reviewed the original Transfusion

Medicine Epidemiology Review application in 2009, when the project was reviewed as research. The application was re-classified as a non-research project when resubmitted to CAG in 2014. This refreshed application has also been submitted as a non-research, public surveillance review, and did not require review by an ethics committee. The original ethical committee approval was based on the assumption that the recipients should not be informed. This had also applied to individuals who had donated blood to those with CJD.

For patients with vCJD, the Department of Health have mandated that recipients of blood donations from those who later developed vCJD are informed. The same health-related feedback was not given to patients who received blood transfusions from those who later developed CJD, and the Group considered whether the two patient groups should be given the same feedback.

The Group asked that the applicants seek advice from an ethics advisor or committee on whether patients who had received blood from a donor later diagnosed with CJD should be informed, and that the feedback received was provided to the CAG for review.

'Patient Notification' and mechanism for managing dissent

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

The applicants advised that they did not have a patient notification strategy. Information about the project would be made available on the NCJDRSU website.

The Group noted that the information provided on the NCJDRSU website was very technical, however members recognised that the applicants had explained a complex subject matter well. Members asked if the website text could also be reviewed by attendees at the family days held by NCJDRSU.

The national blood services also provided information leaflets to blood donors, and information about the surveillance would be included. Members commented that there was potential that donors may interpret mention of the surveillance activity in these leaflets as that there was a risk of contracting CJD via blood transfusions. However, it was expected that this would be appropriately handled by the NHS Blood and Transplant services.

The Group asked that the applicants work with the national blood donor services involved in the proposal in order to determine the most appropriate way of carrying out patient notification. The applicants should also continue to work with the blood services in order to ensure that information on the websites for the NCJDRSU and blood donor services were kept up to date.

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 advised that information about the study would be disseminated on the NCJDRSU website. Information would also be included in scientific publications.

The NCJDRSU also hosted family days, where its projects were discussed. The Group asked that further information on who was invited to these events and the type of information which was shared.

No specific patient and public involvement had been carried out. Members noted that this may be difficult to conduct and determined that, as long as sufficient information was made available about this activity, then the Group would not insist that patient and public involvement was carried out, due to the poor prognosis of this patient group.

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.

Request for further information

1. The data linkages undertaken during the project need to be clarified;

    a. Confirm that the NCJDRSU will disclose confidential patient information to the blood services in England and Wales, and that support is required for this linkage.

    b. Provide assurance that the appropriate approvals are in place for the data linkages taking place in Scotland and Northern Ireland.

c. The NCJDRSU will disclose confidential patient information to NHS Digital and NHS Wales Informatics Service, and support is required for this linkage.

d. The NCJDRSU will request confidential patient information from the medical records of deceased patients, held at GP surgeries and hospitals, and support is required for this.

e. Any other data linkages or activities undertaken using confidential patient information without consent need to be specified,

f. Provide a clear and comprehensive data flow chart which follows the flow of confidential patient information for the purposes of the application activity, identifying where confidential patient information is disclosed between organisations and highlighting which of these disclosures require a recommendation of support under the Regulations.

2. Confirm that data generated from patients in Wales will be linked to datasets held by NHS Wales Informatics Service.,

3. Liaise with the blood services within the UK in order to devise the most appropriate way to operate a communications strategy for the proposal and to ensure that the information made available on the websites of the services is clear and remains up to date. Provide feedback on how this planned activity would be progressed.

4. Further information on the NCJDRSU family days need to be provided, this should include who is invited to these events and the type of information which shared. Feedback on the information shared on the NCJDRSU website also needs to be sought during these events.

5. Advice is to be sought from an ethics advisor or committee on whether patients who have received blood from a donor later diagnosed with CJD should be informed, and feedback from this is to be provided to the CAG for review.

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. 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. **DSPT for University of Edinburgh and National Blood and Transplant Services remain pending.**

Resubmitted Applications – Research

a. 19/CAG/0156 (previously 19/CAG/0095) NAFLD Outcomes

Context

Purpose of application

This application from Newcastle upon Tyne Hospitals NHS Foundation Trust set out the purpose of medical research which seeks to determine the frequency of significant clinical events in patients with Non-alcoholic fatty liver disease (NAFLD).

Non-alcoholic fatty liver disease (NAFLD) is recognised as one of the leading causes of liver disease worldwide, affecting 17-46% of the population in the developed world. The term NAFLD covers a spectrum of liver disease ranging from steatosis, non-alcoholic steatohepatitis (NASH) and end-stage liver disease. NASH occurs in 10-30% of cases and is associated with liver related complications such as variceal bleeding and liver cancers. As well as being associated with increased risk of liver complications, there is also an increased risk of cardiovascular disease, which is most common cause of death in these patients.

This study aims to gain a greater understanding of the natural history of NAFLD by assessing a large cohort of up to 700 patients with biopsies taken over a 30-year period. The long-term outcomes of a group of patients that were diagnosed with Non-Alcoholic Fatty Liver Disease (NAFLD) by liver biopsy at the Freeman Hospital Newcastle in the 1990's and 2000's. Newcastle has a long standing interest in this condition, which is now thought to affect up to 25% of the adult population worldwide, and so this cohort would provide a near unique opportunity to understand outcomes as the patients in this group have been very well characterised during their initial clinical workup and there is a long period of potential follow-up data available.

The applicants had identified three cohorts, amounting to approximately 700 patients, who have previously been treated at Newcastle upon Tyne Hospitals NHS Foundation Trust, who will be included in the study:

1) Patients within the Trust who have agreed to take part in research and would be followed up by the direct care team. This group is out of the scope of the CAG application.

2) Patients who are lost to follow-up. The applicants are seeking support to link to HES and ONS data held by NHS Digital in order to obtain follow up and mortality information.

3) Patients who are deceased. The applicants are seeking support to link to HES and ONS data held by NHS Digital in order to obtain follow up and mortality information.

A recommendation for class 3, 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	700 patients aged 18 years and over, with a diagnosis of non-alcoholic fatty liver disease confirmed on liver biopsy at Newcastle upon Tyne Hospitals NHS Foundation Trust between 01/01/1990 and 31/12/2018. Approximately 300 patients within the Trust have been identified as having died or become lost to follow-up from the Hepatology team, and will be included in this cohort.
Data sources	1. Medical records held at Newcastle upon Tyne Hospitals NHS Foundation Trust 2. HES and ONS data held at NHS Digital 3. GP Summary Care Record
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID number 4. Date of birth 5. Date of death
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Gender 4. Ethnicity

Additional information	The application set out two cohorts. The first cohort included current patients within the Trust, whose follow up information could be obtained locally without linkage to NHS Digital. The second cohort were patients who had not consented to the use of their CPI in research and had since died or been otherwise lost to follow-up. This cohort was the subject of this application.

Confidentiality Advisory Group advice

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

Public interest

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

The Group noted the public interest in the research and raised no queries in this area.

Scope of support

It was unclear whether the 300 patients referred to in the application were the total number of patients who were deceased or otherwise lost to follow-up, or if this number also included patients who the applicants had up-to-date contact information for. The Group requested further clarification on the number of patients included in the cohort that required section 251 support.

Confidential patient information would be disclosed from Newcastle Hospitals NHS Foundation Trust to NHS Digital for linkage with HES and ONS data. The data flow diagram also referenced linkages to the NHS Summary Care Record. Members queried how the applicants would know which GPs to contact if the patients were lost to follow-up. The Group also queried what additional information the applicants expected to gain from the Summary Care Record that could not be found in patients' medical records. Clarification would be sought from the applicant around these points.

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

Eligible patients would have received a liver biopsy at Newcastle Hospitals NHS Foundation Trust at some time in the previous 30 years. A proportion of patients had given consent for use of their information in research and support was not being sought for the inclusion of this group.

The applicants expected that around half of the eligible patients will not have previously given consent to use of their information in research. A number of these patients were expected to have died in the interim period from their diagnostic biopsy until now, and so the research team cannot seek consent. Of the remaining patients, many will have become lost to follow-up from the Hepatology team at the Newcastle Hospitals, and may have moved to a different area of the country.

The applicants noted that tracking patients would involve time and resources, which the research team did not have. Confidential patient information would need to be shared between NHS organisations, GPs and NHS Digital in order to track patients, which would result in greater data sharing and processing than required for the research. For those whose address is known, many may now be elderly or frail, and so the need to complete and return consent forms may be unduly burdensome or cause unnecessary anxiety.

The applicant advised that as complete a dataset as possible was required in order to avoid potential bias. Patients may also be too ill to return the consent form, and the applicants stated that their exclusion from the study may give an inaccurate representation of the long-term outcomes of NAFLD, which would directly impact on the validity on the results.

The Group asked the applicant to clarify the ratio of deceased patients to patients lost to follow-up. The applicants had noted that attempting to trace the contact details of patients lost to follow-up would entail the sharing of more data than is required for the approach proposed by the applicants. Members noted that this justification would not apply for those patients whose current address details were known and assurance was required to understand why consent was not feasible for this cohort.

- Use of anonymised/pseudonymised data

Confidential patient information was required to link information from medical records held in Newcastle upon Tyne Hospitals NHS Foundation Trust to HES and ONS data held by NHS Digital. This linkage cannot be undertaken any other way.

Justification of identifiers

Patients' date of birth and date of death would be retained for analysis. Members asked whether this data would be retained by the applicants. If the data was retained by the applicants, members asked if the dates could be stored in a truncated format, rendering the information less identifiable.

'Patient Notification' and mechanism for managing dissent

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

The applicants held the current addresses for some patients who had not previously given consent and intended to send out an information sheet and notification that their data would be accessed. This information sheet will contain contact details for the research team, should any patient not want to be included or if patients wanted to request further information about their condition and the potential of returning to regular clinical follow-up.

The applicants were seeking support to access confidential patient information for these patients without consent if they did not contact the research team to dissent. The Group queried how many patients the applicants had up to date contact details for, in order to clarify how many would receive direct mailings about the propped activity. The applicants would be asked to provide further information in this area to ensure proceeding on an unconsented basis was justified for this section of the cohort.

The Group queried how many patients the applicants had up to date contact details for, in order to clarify how many would receive direct mailings about the proposed activity

Any individual who did not wish to be included would be excluded from the study. Patients medical notes would be checked for evidence of historic dissent during the review of the notes. If any patient had previously declined to be involved in research of a similar nature (i.e. an observational study) they would be withdrawn from the study.

The applicants planned to place notification materials in relevant clinics. Patients who were lost to follow-up would be unlikely to see these. The applicants had noted a difficulty in placing posters in GP practices, due to the large geographical areas involved in the study. Information would also be displayed on the LIVErNORTH website. The Group asked that information about the study was also included on the Newcastle upon Tyne Hospitals NHS Foundation Trust website.

The Group asked that an address and telephone number was given for patients to contact to register dissent, as well as the e-mail address. The current wording of the poster also referred to linked, anonymised data from records. It needed to be revised to make it clear that confidential patient information would be accessed by the researchers and then anonymised. The poster also needed to include a link to the Participant Information Sheet or contact details if patients wanted to request a paper copy. The poster also referred to ‘CAG approval’, and this needed to be revised to refer to support under Section 251 and its Regulations.

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 methodology of the data collection, particularly in those subjects who are unable to give consent, has been discussed with a patient focus group through the charity LIVErNORTH. Once the results of the study have been concluded, a report of this will be made available through the LIVErNORTH news-letter.

A meeting with LIVErNORTH was held in order to discuss the issue of consent for this study. At this meeting the applicants outlined the aims of the project and the possible methods for obtaining consent. The original methodology for the study, which involved the use of 'opt-out consent', was discussed at this meeting as well as the proposed study documents; Patient Information Sheet and Informed Consent Form. Following this meeting the focus group were happy with the proposed methods for consent and advised on the content of the patient information sheet and consent form.

After feedback from the CAG panel on 10 July 2019 the intended methodology for the study had been amended with the intention of seeking section 251 support to access the data of those patients who had not already consented to taking part in research and removing the opt-out consent proposal. This change in methodology had been discussed with a member of an ethics advisory board and had been presented to another patient advisory group convened by LIVErNORTH. The patient advisory group unanimously voted to support the proposed changes to the methodology of the study.

Following the original discussion with the patient advisory group, the content of the patient information sheet was revised. No further changes were made after a more recent meeting regarding the change in methodology to remove the opt-out consent.

The information given in the Patient Information Sheet was very long and detailed. Members noted that a patient group from LIVErNORTH had reviewed the information sheet and it had been revised following this discussion. Members requested confirmation that this was the case.

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.

Request for further information

1. Clarify the number of patients included in the cohort for which support under Section 251 and its Regulations is sought.

2. Confirm on how many patients in the cohort up to date contact details are held and provide further information in this area to ensure proceeding on an unconsented basis is justified for this section of the cohort.

3. Further information on the data linkage to the Summary Care Record is required;

    a. Explain how the research team will know which GPs to contact, if patients have been lost to follow-up.
    b. Clarify the additional information that will be obtained from the Summary Care Record that cannot be obtain from patients' medical records.

4. Further clarification on the retention of items of confidential patient information required needs to be provided;

    a. Clarify whether patients date of birth and date of death will be retained by the research team.

    b. If so, advise whether these dates can be retained in a truncated form, rendering the information less identifiable.

    c. If the dates need to be stored in full format, justify why this is required.

5. The study poster needs to be amended as follows:

    a. The wording of the poster needs to be revised to explain clearly that confidential patient information will be accessed and disclosed to wider bodies for linkage by the researchers and then anonymised.

    b. A telephone number and postal address as well as email address is to be provided for patients to register dissent.

    c. The poster also needs to contain a link to the Participant Information Sheet or contact details in the event that a patient wishes to request a paper copy.

    d. The reference to 'CAG approval' needs to be amended to refer to support under Section 251 and its Regulations.

6. Confirm if the letter is intended for patients who have not previously given consent. If so, the wording needs to be revised so that it does not refer to consent being withdrawn.

7. The letter and Patient Information Sheet need to include an address and telephone number, as well as an e-mail address.

8. Confirm that the Patient Information Sheet has been reviewed by representatives from LIVErNORTH, and that revisions were made to the Information Sheet following this discussion.

9. Information about the study needs to be provided on the relevant section of the Newcastle upon Tyne Hospitals NHS Foundation Trust website, as well as on the LIVErNorth website.

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 12 July 2019.**

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

4. New applications – Research

b. 19/CAG/0146 Tight K Trial

Context

Purpose of application

This application from Bart's Health NHS Trust set out the purpose of medical research that seeks to determine whether maintaining a normal level of potassium in the blood can help to prevent a fast, irregular heartbeat in patients following CABG surgery just as well as maintaining a high level of potassium.

A fast, irregular heartbeat can occur after heart surgery. This may be dangerous and keep patients in hospital longer. Many doctors believe giving patients potassium helps prevent these irregular heartbeats. However, there is no scientific evidence that such treatment works. Potassium can also be unpleasant for patients to take

and expose patients to additional risk. The aim of this study is to investigate whether it is necessary to administer additional potassium to prevent fast, irregular heartbeats after heart surgery. Maintaining potassium levels at the high end of the normal range is the current standard care for these patients.

The patients approached for this trial would be scheduled to have coronary artery bypass graft (CABG) surgery at participating NHS hospitals. This trial builds on a previous feasibility study, which operated with s251 support under the reference 17/CAG/0087. The feasibility study tested the recruitment methodology which will be operated in this larger scale trial. Members of the research team would screen patients for suitability and make the initial approach about the study. The applicants were seeking support to use the same methodology in this larger-scale trial. Patients would be approached by a member of the research team when they attended clinic prior to surgery. If they are happy to take part, they would be asked to sign a consent form at a clinic visit or when admitted for surgery. As in the feasibility study, screening will be limited to delegated members of the local research team.

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

Confidential patient information requested

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

Cohort	1684 patients aged 18 years and over, undergoing isolated coronary artery bypass grafting (CABG) surgery
Data sources	Medical records held within participating Trusts
Identifiers required for linkage purposes	1. Name 2. Hospital ID number 3. Date of birth 4. Postcode – district level
Identifiers required for analysis purposes	1. Hospital ID number

Confidentiality Advisory Group advice

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

Public interest

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

The Group noted the clear public interest in assessing whether the giving of supplementary potassium was an effective way of regulating patients heart rate post coronary artery bypass graft surgery (CABG). Transfusions take a significant amount of time to complete and it would be useful for clinicians to know if they are necessary in order to reduce costs and the reduce the amount of time spent by staff carrying out treatments that are not useful.

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

Section 251 support was being sought for the research team to undertake the screening process and first approach, to increase the chances that an adequate number of patients would be recruited and so that patients would be approached in advance of their operation and given enough time to consider participating. The applicants were concerned that, if screening and recruitment were carried out by members of the clinical care team, many patients would be missed due to insufficient time in the clinics, or that the patient would be approached close to the date of surgery and therefore be given insufficient time to properly consider the trial.

A pilot trial, using the same recruitment methodology, was supported by CAG in 2017 and had informed the design proposed for this application.

The Group considered whether the screening and recruitment process could be carried out solely by the direct care team. Members suggested that the direct care team could undertake the screening and introduce suitable patients to a member of the research team, who can then explain the research and seek consent.

The Group asked if the findings of the pilot study had indicated that clinicians could undertake the screening process and initial approach to patients, or if it had been indicated that the research team were better placed to carry this out. Members

agreed that this point would be followed up with the applicant to ensure that the outputs of the pilot study supported the requirement for the recruitment to be managed via the research team in the proposed full trial.

The Group noted that the data flow chart implied that the direct care team would be consulted prior to contact with all patients who were due to receive a CABG to confirm appropriateness to approach the patient. The Group queried whether this step was the further screening that was carried out with the patient prior to receiving surgery, which may have impacted on the success of recruitment. 24% of patients screened during the feasibility study had been recruited. 48% had been deemed eligible but not recruited and the remaining patients were unsuitable. The Group queried why such a high number of suitable patients were not recruited and noted that this may have been due to the limitations of the feasibility study. Members also asked if the applicants expected that a similar proportion of suitable patients would not be recruited into this study as well.

The CAG agreed that further clarifications were required from the applicant to address the queries raised in this area to provide assurance that the proposed methodology remained justified for the purposes of the full trial.

- Minimising flows of identifiable information

The applicant confirmed that no patient identifiable data was recorded for the study without the consent of patients and the information accessed during screening was used for patient identification and to contact patients only. Confidential patient information accessed during the screening process would not be accessed again or retained without written consent.

The data flow diagram did not describe what happened to patients who were deemed ineligible. Members requested confirmation that no further action would be taken and the records of these patients would not be accessed again.

- Use of anonymised/pseudonymised data

Access to confidential patient information is necessary to carry out screening of medical records for suitable patients and to make initial contact to seek consent for participation in the study, which could not be otherwise achieved.

‘Patient Notification’ and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as ‘patient notification’. This is separate to the local

obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Patients would be notified of the trial when contacted for consent. Posters, flyers and information leaflets, containing information about the study including how to opt-out, would also be displayed in relevant patient waiting rooms. The Group queried whether patients were likely to have seen the notification materials or otherwise become aware of the study, and if they were able to opt-out prior to screening taking place.

The Group noted that the poster didn't contain much information about the study, but directed patients to read the leaflet, which was more informative. Members asked that the poster was amended to contain further high-level details about the study.

The patient information leaflet needed to be amended to make it clear that records will have been screened for suitability prior to the patient being contacted with information about the study.

The Group queried how many times patients would be contacted by the research team. From the information provided in the application, it appeared that patients were sent a letter, then received a follow-up telephone call, followed by another letter. Members reminded the applicant that, if a patient was approached for consent and did not respond, then this should be considered as dissent, so the proposed number of contacts needed to be finite. This would be clarified with the applicant.

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 patient and public representative was a co-applicant on the trial. They were involved in the design and management of the trial and would also lead the dissemination of the results to patient groups.

Two former patients also sat on the Trial Steering Committee. They had been involved in the feasibility study as committee members, and would provide input into the design and management of the trial.

The feasibility study patient information sheet and consent form had been reviewed by volunteers from three different patient groups, including one for former cardiac surgery patients, and the two patient representatives on the Trial Steering Committee. Their feedback has been incorporated into the trial patient information sheet and consent form, and the screening and recruitment procedures.

Volunteers from three different patient groups also gave their thoughts on the screening process. All were in agreement that this would be acceptable, as long as

the member of the research team was adequately trained for what they were looking for and that it did not bias the trial results.

In terms of recruitment process and documentation, following the feasibility trial, the applicants had made improvements to the patient information sheet and consent form, following feedback from previous cardiac surgery patients and the two patient representatives on the Trial Steering Committee. Site training and Standard Operating Procedures had also been updated to recommend approaching potential patients as early as possible before their surgery. This was in order to reduce the number of declines due to anxiety/nerves around their upcoming surgery, and as suggested by previous cardiac surgery patients.

The applicants would still allow for patients to be approached during admission for their CABG surgery, so that varying hospital schedule schemes and patient transfers were not excluded.

The Group noted that 24% of patients whose records were screened for the feasibility study agreed to take part. A large number of patient records may be screened to order to find the required number of patients, and conducting suitable patient and public involvement and engagement, as well as having a patient notification and dissent mechanism, was necessary. Members asked for confirmation that the use of confidential patient information without consent had been specifically discussed during patient involvement and engagement events.

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.

Request for further information

The CAG is unable to recommend support under Section 251 and its Regulations if a practicable alternative to the proposed methodology is available. The Group noted that there may be an alternative to the screening and consent process being conducted by members of the research team.

1. Consider if it is possible for members of the direct care team to undertake the screening process. The direct care team could screen patient records for suitable patients and then introduce a member of the research team to the patient to explain the project and take consent.

2. If the above is not practicable, please provide justification for this based on the feedback from the pilot study that has been completed.

If the proposed alternative was not practicable, then the following questions need to be addressed;

1. Clarify if further screening was carried out with patients after the record review and prior to receiving surgery, in order to assess their suitability for the project, and whether it was possible that patients could be deemed suitable when the records were screened and then later deemed unsuitable.

2. Clarify how often patients will be contacted about the study.

3. Clarify if it is expected that the proportion of patients screened as suitable and then recruited into the study would be similar to that in the pilot study.

4. Provide confirmation that the records of patients deemed ineligible would not be accessed again.

5. Provide clarification that the use of confidential patient information without consent has been discussed specifically during patient and public involvement and engagement events.

6. The patient notification materials need to be revised as follows;

    a. The information provided on websites needs to explain how patients can dissent prior to screening being carried out.

    b. The poster needs to be revised to include more details about the study.

    c. The patient information leaflet needs to be revised to make it clear that patient records will be screened for suitability prior to patients being contacted with information about the study.

7. The data flow chart needs to be revised as follows,

    a. It needs to be made clear when patients will be screened and when they will be given the opportunity to dissent.

Specific conditions of support (Provisional)

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

1. Favourable opinion from a Research Ethics Committee. **Pending**

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 for Bart's Health NHS Trust**

4. New applications Non-Research

b. 19/CAG/0147 – An exploratory descriptive analysis of the 5-year survivorship of total ankle replacements compared with equivalent rates in administrative datasets with further adjusting for co-varieties

Context

Purpose of application

This application from the Royal Devon and Exeter NHS Foundation Trust set out the purpose of a service evaluation to determine the five-year survivorship of total ankle replacements.

Over 650 total ankle replacements (TAR) are recorded in the National Joint Registry each year. There have been varying results reported with these implants, and considerable research is ongoing in assessing long term outcomes of these replacements and comparing total ankle replacements with ankle arthrodesis. A previous systematic review on long term outcomes of ankle replacements found that TAR had a positive impact on patients' lives but was unable to make strong conclusions as these previous studies had been small-scale.

This service evaluation aims to determine the failure rate of ankle replacements. A failure is determined as revision, arthrodesis or amputation. This will enable further information to be to be given to patients when considering ankle replacement and inform surgeons of the likely outcomes for these patients. It will also determine risk factors for ankle replacement failures.

The NJR will disclose confidential patient information to NHS Digital to facilitate linkage with HES/ONS. The linked, anonymised dataset will be returned to the applicant for analysis.

A recommendation for class 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	Patients who underwent ankle replacement surgery in the UK that are recorded on the NJR between 01/01/2010 and 31/12/2018. It is estimated that 5,500 patients will be included.
Data sources	1. National Joint Registry 2. HES/ONS data held by NHS Digital
Identifiers required for linkage purposes	1. NHS number 2. Individual anonymised number 3. Age 4. Sex 5. Date of admission 6. Indication for primary procedure, previous infection, previous fracture, previous surgery, ankle ROM, associated procedure, side 7. ASA grade: 8. Implant data/ brand / manufacturer: 9. Revision codes 10. Below knee amputation 11. Site code for the ankle joint combined with fusion codes 12. 30 day and 1-year mortality
Identifiers required for analysis purposes	1. Individual anonymised number 2. Age 3. Sex

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.

Ankle replacement surgery was a relatively new procedure, compared with hip and knee replacements, and little information was currently available on rates of failure and complications. The rate of ankle revisions reported via the NJR was currently 6.65%, but ankle revisions may be under-reported, particularly if an ankle joint fusion or below knee amputation was needed.

Accurate information on the failure of ankle replacements was needed to aid patients and clinicians when making treatment decisions. The Group noted that establishing a baseline in this area had a clear public interest.

Categorisation of the project

The CAG considered whether the project should be considered as research or as a non-research service evaluation.

The treatment outcomes were currently unknown, and the applicants sought to produce new scientific knowledge. The results were also transferable, which suggested that the project was research. The applicant was also relying on information materials given by patients when agreeing to be included in the NJR, which referred to the use of data in future research projects.

The Group advised that the applicant access the information and decision tools which were available on the Health Research Authority's website to assist in determining whether the project has been correctly categorised as a non-research proposal. Feedback from this needed to be provided as part of the revised application.

Data flows

Further information on the data flows of the project were required, in order to understand the scope of the support requested.

The data flow diagram referenced disclosures straight from the NJR to the Royal Devon and Exeter NHS Trust. The Group requested further clarification on this disclosure, and if any items of confidential patient information were included in the data for use in subsequent linkage. The applicant would also be asked to provide a data flow chart to support the narrative overview of the data flows to support the study.

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 explained that consent was impracticable, as the monitoring outcomes were collected via national databases from multiple sources over long periods of time. Patients would be tracked across organisations, as they may be treated at different hospitals and clinics. In the absence of such cross-checking, patients could be double-counted, and analyses would become unreliable.

When patients were first recruited into the NJR they were informed that they would be contacted if their information was to be used in wider research. The applicants were linking to NHS Digital in order to obtain further information from HES and ONS. The CAG considered whether patients consent for inclusion the NJR also covered this disclosure of confidential patient information from the NJR to NHS Digital, or if patients should be contacted to be informed that the linkage was taking place.

The CAG asked the applicant to clarify why the process of contacting patients about additional use of data described in the NJR consent form was not followed for this project.

- Use of anonymised/pseudonymised data

The applicant explained that the use of confidential patient information had been minimised as much as possible. Only the National Joint Registry and NHS Digital, who provided the data, and the administrative staff performing pseudonymisation, were able to access confidential patient information. Individual patients were given a trial number for anonymisation and no confidential patient information was transferred to the applicant. The Group accepted the explanation given and raised no queries.

Justification of identifiers
The Group queried the identifiers required. The applicants were collecting the age of patients, and members asked it the exact age was needed or if year of birth could be used instead. If the exact age was required, justification for this needed to be provided.

'Patient Notification' and mechanism for managing dissent
It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and

to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicant provided the consent form for the National Joint Registry, which contained information on how patients could dissent from inclusion in the NJR. No notification materials or information on how patients can dissent from this study specifically were provided.

The Group asked the applicant to liaise with the NJR to explore the potential of establishing a specific patient notification and dissent mechanism for this 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 applicant advised that this project had been discussed with several patients that have had ankle replacements performed or were suffering with ankle osteoarthritis. The patients had noted that they would like to be given further information on the likely outcomes of ankle replacements and the survivorship of the implant. They were also interested to know if there were any risk factors that they had that would affect their chances of needing a further operation. This question had therefore been added to the outcomes.

The Group requested that more information on what was discussed at these events was provided, including whether the use of confidential patient information without consent had been specifically discussed.

If the applicants decided not to seek consent from patients, then the views of the patient cohort need to be sought about the use of confidential patient information without consent.

General Data Protection Regulation (GDPR)
The Group considered the answers given to the questions on how the seven principles of the GDPR had been met and determined that fuller responses were needed as the detail currently provided did not account for the disclosure and processing of confidential patient information undertaken by NHS Digital.

Confidentiality Advisory Group advice conclusion
In line with the considerations above, the CAG agreed that, whilst supportive of the proposal in principle, due to the clear medical purpose and public interest in the proposed activity, it was unable to provide a recommendation of support where it appeared a practicable alternative was available.

The applicant is asked to consider the below guidance around a potential practicable alternative to enable the project to proceed without the requirement to seek support under the Regulations in the first instance.

1. The NJR consent form explains that if researchers wish to collect data in addition to that available in the NJR then patients will be contacted. If contact will not be made, then justification for this needs to be provided.

Request for further information

If progressing with the CAG application, the following additional points would need to be addressed:

1. Consider whether the application has been appropriately submitted as a non-research project. Guidance on the HRA website regarding how projects are categorised as research or non-research should be consulted.

2. Clarify the data disclosure directly from the NJR to the Royal Devon and Exeter NHS Trust, and if any items of confidential patient information will be directly shared.

3. Explore the potential of establishing a project-specific communication and dissent mechanism with the NJR. Provide feedback from this

4. Further information on the patient and public involvement and engagement events carried out needs to be provided;

    a. This should include whether the use of confidential patient information without consent was discussed.

    b. If consent was not to be sought from patients, the views of the patient cohort on the use of confidential patient information without consent need to be obtained.

5. Provide justification for collecting the exact age of patients, rather than year of birth.

6. Further information on how the seven principles of GDPR will be met needs to be provided.

7. Amendments – Non Research

b. 18/CAG/0146 (previously PIAG 2-05(j)/2006) - National Joint Registry

Context

Purpose of application

The National Joint Registry, commissioned by the Healthcare Quality Improvement Partnership, was originally granted Section 60 support in June 2006. Support has been ongoing since this time.

Support under the Regulations currently extends to the following three specific purposes:

1. To collect confidential patient information where a patient record indicates 'Not recorded' for consent.

2. To use patient identifiers to link procedures recorded on the NJR to other healthcare datasets where patient consent is recorded as 'yes' and 'unknown'. The third-party datasets include data from HES, PROMs and ONS data provided to the NJR by NHS Digital in relation to the relevant OPCS4 codes for the reporting periods from 2014 up to and including 2017. Confidential patient information is disclosed from NHS Digital to Northgate Public Services for linkage with the NJR records.

3. To retrospectively obtain confidential patient information without first gaining patient consent where there is a specific and clear issue with regards to patient safety.

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

Confidential patient information requested

Cohort

The National Joint Registry collects data on all hip, knee, ankle, elbow and shoulder replacement operations carried out in NHS and independent sector hospitals and treatment centres in England and Wales from 1 April 2003 onwards. The CAG remit extends to those patients whose consent status is unknown within the registry.

The following items of confidential patient information were requested for the purposes set out below:

- Surname – for data linkage,
- Forename – for data linkage,
- Date of Birth – for data linkage and analysis,

- Home address including postcode – for data linkage and analysis,
- NHS Number or national identifier – for data linkage,
- Gender – for data linkage,
- Date of death – data for linkage and analysis.

Confidentiality Advisory Group advice

Public interest

The CAG recognised that the application established an appropriate medical purpose through the management of health and social care services. Members were assured of the ongoing public interest in the work of the National Joint Registry and raised no queries in this area.

Purpose of the Application

The Group acknowledged that support under the Regulations had been in place to support the National Joint Registry had been ongoing since June 2006, in which time several amendments had been made to the scope of support. The applicant was asked to provide a refreshed application submission which consolidated the existing scope of support into a single application to ensure an accurate and up-to-date record was available and to bring the application in line with current standards.

Scope of Support

The CAG recognised that an amendment had received a recommendation of support in June 2017 which provided support under the Regulations for the disclosure of confidential patient information from NHS Digital to the NJR in relation to all relevant OPCS4 codes for the reporting periods from 2014 up to and including 2017. A condition had been added to the scope of this support to explore the potential for data linkage to be undertaken by NHS Digital. However, following receipt of an appeal from the applicant, this condition was waived in February 2019.

The refreshed application had requested ongoing support under the Regulations for this disclosure and linkage of confidential patient information; however, Members noted that the patient facing information materials and consent form provided clear information around this data linkage. The information leaflet was dated June 2018 which suggested that this had been updated in the intervening period; however, the consent form provided was dated August 2014.

The CAG recognised support under the Regulations could not be recommended where a practicable alternative was already in place, in relation to the common law duty of confidentiality, to legitimise the processing. Members were of the opinion that the consent taken from patients included in the Registry on this basis provided a legal basis to legitimise this data linkage. It was agreed that further information was required from the applicant to understand why the revised application had requested

ongoing support for this data flow, when there appeared to be a practicable alternative of valid consent already in place.

The Group was content to provide continued support to this disclosure and data linkage in relation to the sub-cohort of patients for whom consent status was unknown or recorded as no.

Practicable alternatives

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

- Feasibility of consent

The Group acknowledged that data collection for the National Joint Registry was undertaken in most cases with patient consent. The latest annual consent rates recorded were reported as: ‘Yes’ - 92.3%; ‘No’ - 1.4%; ‘Unknown’ - 6%, which was recognised as high attrition rate.

Members were also considering an associated application for use of data collected for audit purposes within the NJR for research purposes. This application had raised questions around how inclusion within the registry was being managed for patients who lacked capacity to consent for themselves. The CAG agreed that the implications of these queries carried over into the audit application on the basis that initial consent approach related to the non-research purposes. It was agreed that further clarity was required from the applicant in this area.

- Use of anonymised/pseudonymised data

The CAG recognised that confidential patient information was required for sample verification and linkage with wider NHS datasets which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The Group were assured that the items of confidential patient information requested continued to be appropriate and proportionate to achieve the aims of the audit and raised no queries in this area.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and the Data Protection Act 2018. The Group considered the patient facing information and consenting documentation which had been provided to support the application. It was noted that

the documentation did not made it clear that confidential patient information would be recorded for those patients who did not provide an active consent or dissent to their inclusion on the Registry.

Members commented that in the consent form, it was specifically noted that personal information would only be recorded if consent was provided, which did not accurately reflect that support under the Regulations was in place to collect confidential patient information for patients whose consent status was unknown. It was agreed that the patient facing information and consent materials should be updated to provide a clear overview of what information would be collected in the event that consent is not actively recorded or dissented.

Confidentiality Advisory Group advice conclusion

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

Further Information Required

The CAG had identified some areas requiring further clarification when considering the refreshed application which required further response from the applicant.

Request for further information (Summary)

1. Explain why support under the Regulations has been requested to legitimise the disclosure of confidential patient information from NHS Digital to the National Joint Registry in relation to patients who were included in the Registry on a consented basis.

2. Clarify what protocol is in place to include patients on the Registry who lack capacity to consent for themselves.

3. The patient information and consent materials should be updated to include clear information around the collection of confidential patient information with support under the Regulations for those patients whose consent status is unknown. Revised documentation should be provided for consideration together with an overview of the plan to disseminate this amongst participating Trusts and Health Boards.

Specific conditions of support

1. All pre-existing conditions of support related to PIAG 2-05(j)/2006 remain applicable.

2. The pre-existing annual review cycle remains applicable, with the next annual review to be received 4 weeks before 12 November 2019, and then on an annual basis to this schedule.

3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed: Northgate Public Services has a satisfactory reviewed score for IGT v14.1 2017-18)**

8. Minutes of the meeting held on 4 July 2019

The minutes of the meeting held on 04 July 2019 were not reviewed as an outcome is pending.

9. Any other business

No other business was raised.

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

Signed – Chair	Date

Signed – Confidentiality Advice Team	Date