Minutes of the meeting of the Confidentiality Advisory Group

10 February 2022

Held via zoom

Present:

Name	
Dr Tony Calland MBE	CAG Chair
Professor William Bernal	CAG alternative vice-chair
Dr Sandra Duggan	CAG member
Mr David Evans	CAG member
Dr Liliane Field	CAG member
Dr Katie Harron	CAG member
Professor Jennifer Kurinczuk	CAG member
Mr Andrew Melville	CAG member
Professor Sara Randall	CAG member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor
Anne Reddaway	HRA Programme Manager (Observer)

1. Introduction, apologies and declarations of interest

Declarations of interest:

Item 3c 22/CAG/0014 - Professor Will Bernal noted that he submitted data to TARN as part of his professional role. He was not chairing this item and the CAG agreed that he could remain in the meeting during this discussion.

item 3d - 22/CA/0010 – Professor Jenny Kurinczuks worked in the same organisation as the applications but had no involvement with the application and had no connection to the University department. The CAG agreed that she could remain in the meeting during this discussion.

2. Support decisions

Secretary of State for Health & Social Care Decisions

No non-research applications were discussed at the **02 December 2021** meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **02 December 2021** meeting applications.

3. New applications

a. 22/CAG/0015 - REDCap registry for the UK highly specialised national service for Bardet-Biedl syndrome

Context

Purpose of application

This application from University College London set out the purpose of creating a registry to aid in the NHS delivery of highly specialised services for Bardet-Biedl syndrome (BBS).

Approximately 620 people in the UK have a diagnosis of BBS. Bardet Biedl Syndrome is a rare genetic disorder with highly variable symptoms which may include retinal degeneration, obesity, reduced kidney function, polydactyly (extra digits of the hands or feet) among many other features. Around 190 of those affected are under 18 years of age. The national Bardet-Biedl Syndrome service was commissioned by NHS England Highly Specialised Services in 2010, with a view to improving the diagnosis of BBS, gaining a better understanding of the natural history, preventing and treating secondary sequalae and to ensure that the BBS community are in the best position to access novel therapies as they are developed. Clinicians from the four national commissioned BBS service centres have collaborated with BBS UK, the support group for patients with BBS, to develop a REDCap based registry. This registry will be used to audit, review and update the management of BBS locally and nationally. The applicants also intend to make the registry available for research purposes, in order to develop knowledge of the natural history of BBS and to create novel therapies.

Data managers at the four nationally commissioned BBS services centres will manually enter confidential patient information into the REDCap registry. The REDCap registry will be held within the University College London data safe haven and data will be processed by a central data manager. Clinicians directly involved in the clinical care of BBS patients may apply for read-only access to the database via the BBS access committee.

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

Confidential patient information requested

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

Cohort	Patients in England with a diagnosis of Bardet-Biedl syndrome and attending a BBS clinic from 12th of May 2010 onwards.
Data sources	1. Patient records held at: a. Great Ormond Street Hospital for Children NHS Foundation Trust, b. Guy's and St Thomas' NHS Foundation Trust, c. University Hospitals Birmingham NHS Foundation Trust d. Birmingham Women's and Children's NHS Foundation Trust.
Identifiers required for linkage purposes	1. Patient name 2. Date of birth 3. Gender 4. Ethnicity
Identifiers required for analysis purposes	1. Patient name 2. Date of birth 3. Gender 4. Ethnicity Full dataset included in Appendix 1

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 CAG agreed that the application had a medical purpose and was 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 applicants advised that consent was not feasible as some patients will have died or will not be attending clinics. The applicants also explained that they expected that only 50% would respond to requests for consent and that complete case ascertainment was required to gain a comprehensive and unbiased overview. The CAG noted that this was based on response rates to questionnaires or surveys. Patients diagnosed with BBS will have gone through a long and complicated process and will have attended hospital many times. This presented several opportunities for patients to be approached and given information about the registry. The CAG asked that the applicants consider whether seeking consent prospectively from patients was possible, while support under s251 was given for retrospective patients.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to validate the information and identify duplicate records. For audit purposes, clinicians need to be able to identify and view data for patients treated at their service, and so patients moving between centres can be tracked. The CAG agreed that the activity could not be conducted in any other way.

'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 advised that all patients will be emailed with information about the registry and advised on how they can request to be opted-out. Information about the registry

will also be included in the patient support groups twice-yearly magazine. The “Information and Opt-Out Leaflet” was provided. This contained an email address. The applicants advised that a telephone number and postal address would be added. The applicant advised that the text used in the patient leaflet would also be used in the patient magazine and email notification.

Any patient who expresses a wish not to take part via telephone, email or face to face contact, will immediately be removed from the registry. The applicants will also undertake a six-monthly update with NHS Digital to ensure that any objections lodged centrally by any patients are respected. NHS Digital will apply the National Data Opt-Out.

The CAG agreed that further work was needed on the patient notification. The applicants had advised that all patients would be emailed with information about the study. The CAG queried whether the applicants would hold email addresses for all patients and what would happen if they did not, e.g. will information about the registry be posted to patients.

Information about the registry will be included in the twice-yearly magazine. The CAG asked whether this information would be included for the foreseeable future.

Patients who were added to the registry in childhood would need to be given information about the study when they reached adulthood. The CAG asked if applicants had considered this

The CAG agreed that the patient facing information needed to be written in plain English. The leaflet also needed to be provided, rather than the text only. The CAG also noted that many patients with BBS would have some form of learning disability. Members asked that the patient notification materials were reviewed during further patient and public involvement.

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 they had consulted with BBS patient support group BBS UK on the set up and format of the registry. Due to the pandemic this took place via MS teams calls. They provided input on information they felt would be of additional value to the registry particularly including information on developmental stage and whether and EHCP was in place, but was not originally planned to be collected from the notes retrospectively. During the development of the database, the applicants have regularly consulted with BBS UK regarding their views on the registry and the consenting process.

The discussions with BBS UK had included the issue of not seeking consent. BBS UK were supportive of the approach proposed by the applicants, as this is most likely to achieve a full overview of the natural history of the condition. BBS UK have over 20 years of experience of working with the patient group and are of the opinion that the BBS community is fully supportive of the registry, but that consent uptake may be low. A letter of support from BBS UK was provided.

The CAG requested further clarification on the number of people involved in the patient and public involvement group.

The CAG also noted that many patients with BBS will have some level of learning disability and asked that further patient and public involvement was conducted to include review of the patient notification documents to ensure they are suitable for the intended audience.

Feedback from the further patient and public involvement needed to be provided within 6 months of the issuing of the conditional outcome letter.

Exit strategy

The applicants intend to retain confidential patient information indefinitely for the benefit of the BBS patient population. This will be linked to the BBS national clinics for as long as they are supported by the NHS highly specialised services and, if these are discontinued, to continue to support the patient group. The CAG raised no queries under this heading.

Class support required

The CAG agreed that classes 1 and 4 support were required, as well as 5 and 6.

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 Secretary of State for Health and Social Care, 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. Consider whether seeking consent prospectively from patients is possible, so that support under s251 is only required for patients included retrospectively

2. Consider whether patients NHS numbers should be included.

3. Clarify whether the applicants hold email addresses for all patients and what would happen if they did not, e.g. will information about the registry be posted to patients.

4. Clarify whether information about the registry will be included in the twice-yearly magazine for the foreseeable future.

5. Explain how patients included in the registry as children will be informed about the study when they reach adulthood.

6. The patient facing information needs to be written in plain English.

7. The finalised version of the leaflet needs to be provided, rather than the text alone.

8. Provide clarification on the number of people involved in the patient and public involvement group.

9. Further patient and public involvement needs to be caried out, including review of the patient notification materials to ensure the language used is suitable.

10. Feedback from the above needs to be provided within 6 months of the issuing of the conditional outcome letter.

11. 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 D**SPT reviews for **University College London, Great Ormond Street Hospital for Children NHS Foundation Trust, Guy's and St Thomas' Hospital NHS Foundation Trust, University Hospitals Birmingham NHS Foundation Trust and Birmingham Women's and Children's NHS Foundation Trust**, were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 February 2022).

b. 22/CAG/0011 - The Norfolk Arthritis Register (NOAR)

Context

Purpose of application

This application from the University of East Anglia set out the purpose of medical research to study the natural history of arthritis and to identify genetic and non-genetic factors, which may be related to the onset of arthritis, response to treatment and long-term outcomes.

The Norfolk Arthritis Register (NOAR) was set up in 1989 as a large community-based study investigating the cause and outcome of inflammatory polyarthritis. So far, data on over 4900 participants has been collected, and recruitment is continuing. The application was originally supported by the CAG under reference ECC 4-02(FT1)/2012. A refreshed application has been submitted at the request of the CAG.

All patients who are newly diagnosed with an inflammatory arthritis, presenting via primary or secondary care, should be referred to NOAR. New referrals are checked for eligibility and patients are then contacted by the study team by telephone and verbal consent sought to send out the study information. This information contains a consent form and participation would proceed on a consented basis.

The applicants will also be undertaking linkage to HES and ONS mortality data. The NOAR ID, NHS number, postcode, sex and date of birth for all identified NOAR patients will be extracted from the NOAR database. Two separate data extracts will be created, one list which will be processed under s251 and another list where patients have given explicit consent. Both lists will be transferred to NHS Digital for linkage to HES and ONS data. The National Data Opt-Out will be applied and the all identifiers other than the NOAR ID removed. The dataset will then be transferred to the University of Manchester Data Safe Haven.

The applicants seek support for the transfer of confidential patient information for newly diagnosed patients to the NOAR team, so that eligibility can be checked, and contact made. Support is also sought for the further access, retention and reuse of mortality records supplied by ONS between 2003 and 2017 for patients recruited before 2003 or after 2015. Support is also sought for the further access, retention and reuse of HES data, supplied between 2000-2017 for participants recruited prior to 2015 who have not been reconsented. S251 support is also sought to provide an ongoing legal basis for participants who have died or been lost to follow up.

The applicants were given support in 2012, under reference ECC 4-02(FT1)/2012. The applicants were asked to submit a refreshed application when they submitted their annual review in 2021. This was because no annual reviews had been submitted since 2016 and there was a lack of clarity over the activities that the original support covered.

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

Confidential patient information requested

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

Cohort	Patients aged 16 years and over who meet the below inclusion criteria: Have had two or more swollen joints, lasting for 4 or more weeks. Have a clinician diagnosis of an Inflammatory Arthritis. Resident in Norfolk at time of symptom onset and registered with participating GP Practice. Onset in the last 2 years. Willing to give informed consent to take part in the study. 5330 are estimated to be included.
Data sources	1. NOAR Participants (questionnaire data) 2. GP's within Norfolk and Waveney CCG 3. Norfolk and Norwich University Hospital NHS Foundation Trust patient and clinical data (PAS, ICE, patient notes) 4. NHS Digital data - a) Hospital Episodes Statistics (HES) b) Office for national Statistics (ONS) mortality data 5. European Prospective Investigation into Cancer (EPIC)

Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Postcode – sector level 4. Sex
Identifiers required for analysis purposes	1. Postcode – district level

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 noted that the application had a medical purpose and was in the public interest.

Scope

The applicants required support to collect confidential patient information from NHS Digital for patients who had been consented, but whose existing consent had been determined by NHS Digital to not cover this linkage, until these patients could be recontacted for consent. The CAG noted that patients recontacted for consent may dissent or not-respond. Non-response would mean that patients should be considered as dissenting and require the removal of their data.

The CAG agreed that they would be supportive if patients already included in the register, but whose consent did not cover the linkage to NHS Digital, were not re-consented. All new patients recruited would give explicit consent to the linkage to NHS Digital.

Practicable alternatives

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

- **Minimising flows of identifiable information**

The applicants sought to obtain patients' full postcode from NHS Digital. It appeared that this was needed for deprivation scoring and the CAG queried whether the applicants needed the full postcode, or whether NHS Digital could provide the deprivation scoring.

- **Feasibility of consent**

The applicants advised that they had discussed whether consent could be sought with NHS Digital when preparing the application. Support under s251 is required for the further access, retention and reuse of mortality records supplied by ONS between 2003 and 2017 for patients recruited before 2003 or after 2015. Support is also sought for the further access, retention and reuse of HES data, supplied between 2000-2017 for participants recruited prior to 2015 who have not been reconsented. S251 support is also sought to provide an ongoing legal basis for participants who have died or been lost to follow up.

It is not possible to seek consent for patients who are deceased or have been lost to follow up. It is also not practicable to re-consent patients who have completed their follow-up, as this is prohibitive on cost and resource grounds.

Using the new consent form, participants still in touch with the study will be re-consented to give explicit consent to obtain HES and mortality data. New participants will also give explicit consent. As noted above, the CAG was supportive of existing patients not being re-consented for this data linkage.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link the NOAR database to enable NHS Digital to identify the correct participants and link to their mortality and HES data. The NOAR team also require access to confidential patient information to check the eligibility of newly diagnosed patients and make contact to seek consent to be involved in the Register.

'Patient Notification' and mechanism for managing dissent

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

This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A Privacy Notice will be available on the NOAR website and the text of this notice was provided. The applicants explained that a record will be kept of patients who dissent so that no further information is collected from their medical records. Information on how patients can request the removal of their data is included in the NOAR Privacy notice. Email and postal contacts were provided on the Privacy Notice. Information will also be displayed on the NOAR website.

The CAG agreed that it was difficult to find the Privacy Notice on the project website. Members asked that the Privacy Notice was displayed more prominently.

The CAG noted that the Privacy Notice contained a table, which described the different variables used and where they were obtained from. Members noted that the terms “sex” and “gender” were used interchangeably, and members asked that the terms were revised for consistency and accuracy.

The Patient Notification needed to be proofread. Members noted that the notification explained that patient identifiers would be replaced by the study ID wherever possible. It was not clear under what circumstances it would not be possible to replace identifiers with the study ID. This needed to be explained in the Patient Notification materials. It also needs to be explained that support under Regulation 5 of the COPI Regulations (s251 support) is in place.

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 NOAR have undertaken close involvement with patient groups in the design of data collection, in the interpretation of data and in the dissemination of findings. NOAR holds an annual Management meeting to which at least two participant contributors are always invited. NOAR also holds an Annual Scientific meeting to which research participants are invited, along with clinicians and other academics, where everyone can have their say on the direction of future study.

Currently, four patient partners are advising on the content and wording of a new NOAR Patient Information Sheet, Consent form and Privacy notice. Participants are always included as the “co-producers” in the formulation and conception of any new research ideas.

The CAG agreed that further information was needed on the patient and public involvement undertaken so far. The CAG noted that two patient contributors were invited to each annual management meeting. Members queried whether the same two patient contributors were invited each year, or if a process for requesting and selecting volunteers was in place.

Four members of the Patient and Public Involvement panel had been asked specific questions about the linkage to HES and mortality data without consent. Only 2 panel members had responded to the questions, who responded positively. The CAG asked that further patient and public involvement was carried out with a larger group.

The CAG agreed that a Patient and Public Involvement group needed to be created. This group needed to be consulted over the use of confidential patient information without consent and undertake review of the patient notification materials.

Exit strategy

The applicants explained that consent would be sought where possible, i.e. when annual contact is made with those still in contact with the applicants. The participant information sheet and consent forms have been revised to seek explicit consent to obtain HES and mortality data, and these documents will be used to recruit new participants.

Consent process

The Consent Form contained 21 separate clauses. The CAG noted that Clause 3 stated that “I understand that if I choose to withdraw from the study, the data and samples I have already provided will be retained by the NOAR team for ongoing data analysis.” The CAG noted that patients could not request to completely withdraw from the study, as the applicants would retain data.

Confidentiality Advisory Group advice conclusion

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

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

Further information required

1. Clarification is needed on the scope of support sought. Consider whether the support sought should cover all patients recruited so far, whose consent did not cover the linkages to NHS Digital. All new patients recruited would give explicit consent to the linkage to NHS Digital.

2. Consider whether the full postcode is needed or whether NHS Digital can provide the deprivation scoring information.

3. The following changes to the Patient Notice are required;

    a. The Privacy Notice needs to be displayed more prominently on the website.

    b. The terms “sex” and “gender” in the table need to be revised for consistency and accuracy.

    c. It needs to be explained in the Privacy Notice that support under Regulation 5 of the COPI Regulations (s251 support) is in place.

4. Further information needs to be provided on the patient and public involvement undertaken so far.

5. Clarification needs to be provided on whether the same two patient contributors were invited to the annual management meeting, or if a process for requesting and selecting volunteers was in place.

6. Further patient and public involvement needs to be carried out with a larger group. This group needed to be consulted over the use of confidential patient information without consent and undertake review of the patient notification materials.

7. The Consent Form needs to be revised to make it clear that patients could not request to completely withdraw from the study, as the applicants would retain data.

c. 22/CAG/0014 - The Trauma Audit & Research Network (TARN) (supersedes ECC 7-05(g) 2011 and PIAG 3-04 (e) 2006)

Context

Purpose of application

This non-research application submitted by Trauma Audit and Research Network (TARN), based at The University of Manchester, sets out the purpose of auditing trauma care in England, Wales, NI and Ireland, for the purposes of monitoring standards of care, providing accurate outcome analysis, and facilitating improvements for the treatment of trauma patients. This CAG application is only relevant for English and Welsh data.

Traumatic injury is a global burden and largely contributes to death and disability across the UK. TARN aims to facilitate the development and improvement of trauma services, thereby reducing the associated burden of death and disability.

TARN was initially established in 1990. As support was initially recommended many years ago, and there have been many amendments to this support, CAG requested that a new application was made. This refreshed application for TARN will supersede both ECC 7-05(g)/2011 and PIAG 3-04 (e) 2006, as all the processes covered by the ECC and PIAG applications are included in this refreshed application.

TARN have existing ‘s251’ support to collect confidential patient information from participating Trusts, and retain patient NHS numbers and dates of birth to support specific activities as a national clinical audit in England and Wales. The specific activities that require these identifiers include;

- providing participating Trusts with case mix standardised outcome analysis and comparisons of care for clinicians, NHS governance and commissioners to drive improvements,
- linkage with HES and PEDW trauma data for validation and to assist with data completeness across hospitals,
- linkage with PROMS data,
- Outcome prediction modelling that require data linkage with ONS to obtain true 30 day patient outcomes.
- TARN also provides data for specific Welsh projects that link with SAIL data, but this is not disclosed back to TARN.

TARN also supports the implementation of the Best Practice Tariff, however any data flows regarding this do not require ‘s251’ support, as these are undertaken with NHS England Directions as the legal basis.

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	Trauma patients attending Major Trauma receiving Hospitals in England and Wales 1)Trauma patients: Irrespective of age 2) Who fulfil one of the following length of stay criteria: • In hospital for >3 overnight stays • Admitted to a Critical care area (regardless of LOS) • Transferred out for specialist care or repatriation (total LOS >3 overnight stays) • Transferred in for specialist care or repatriation* (total LOS >3 overnight stays) • Deaths (including deaths in ED, even if COD is medical) 3. AND whose isolated injuries meet one of the following criteria>>). **3) And** whose injuries fulfil the following criteria: • All head, complicated facial, spinal, organ or vessel injuries • Any open limb injury or any 2 limb fractures &/or dislocations. Irrespective of the length of stay criteria, patients with the following injuries are excluded: • Isolated femoral neck or single pubic rami fractures aged 65 years or greater • Simple skin injuries including uncomplicated penetrating injuries • Closed unilateral limb fractures

Data sources	2. 218 participating hospitals – those in England and Wales are in scope for 's251' ,Northern Ireland and Ireland are out of scope for 's251'. 3. HES and ONS (NHS Digital) 4. Major trauma PROMS (quality health) 5. Patient Episode Database for Wales (PEDW) (DHCW) SAIL and SUS data are not disclosed back to the applicant, and are not data sources for the TARN application.
Identifiers required to be collected by participating Trusts and disclosed to TARN, and retained by TARN	<u>Direct</u> identifiers collected: 1. NHS number 2. Date of Birth Additional data collected: 3. Age 4. Sex 5. Incidence postcode 6. Partial patient postcode (first part and first digit of second part) *(Patient Name and Full patient postcode are encrypted at source and only the submitting hospitals can view this data)*
Identifiers required for linkage purposes	For linkage by TARN to HES, ONS, PROMS, PEDW; 1. NHS number 2. Date of Birth Provided to DHCW for linkage with SAIL: 1. NHS number 2. Date of birth 3. Sex Provided to CSU for linkage with SUS (with NHS Directions as legal basis): 1. NHS number

	2. Date of Birth 3. Partial postcode 4. Encrypted name
Identifiers required for analysis purposes	Direct identifiers required: 1. NHS number 2. Date of Birth Additional data required: 3. Age 4. Sex 5. Incidence postcode 6. Partial patient postcode (first part and first digit of second part)

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 Members agreed that the activity is in the public interest.

Practicable alternatives

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

- **Feasibility of consent**

The applicant has put forward two main justifications for consent not being a practicable alternative. The first is the requirement for a truly comprehensive audit - patients often arrive in a severely injured or unconscious state or die soon after admission and in that

situation it is not possible to obtain patient consent. By excluding patients who were unable to give consent a large proportion of injured patients would be affected, and in turn would have huge implications on how best to monitor standards and trauma care delivery. Additionally the exclusion from the audit of patients unable to give informed consent would automatically exclude a large proportion of patients, greatly reducing the potential impact of the audit in the overall improvement of care. The second justification provided surrounds the need to protect the most vulnerable patients - the potential adverse impact on the care of patients unable to consent could be quite damaging. In order not to disadvantage such patients, their inclusion is essential. An example would be exposing them to prolonged and hurtful pre-operative delay that was not audited as part of TARN, and therefore less likely to be addressed as an important service issue. The Members agreed that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage, and to be able to identify the correct patient, for example, during the validation process. It is not possible for the applicants to undertake the processes required using pseudonymised information.

Justification of identifiers

NHS numbers will be retained for three years and then deleted. This is the same as the current TARN application. Date of birth is retained indefinitely. The Members were not clear why NHS number was required to be retained for a time period of 3 years. The Members were also not clear why date of birth is required to be retained indefinitely. Justification is to be provided as a condition of support.

'Patient Notification' and mechanism for managing dissent

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

A patient Information leaflet/flyer is on the TARN website and links to a longer privacy section on the website, where it states what information is collected and how patients can opt out. The flyer clearly states that 's251' is the legal basis for processing.

The National Data Opt Out policy is also on TARN's website and available to general public. The National Data Opt Out is applied, both by NHS Digital, and also at Trust level - Hospitals are advised not to submit patients who have opted out to TARN. The HES data received from NHS Digital excludes opt out patients, therefore there should be no impact on case ascertainment percentage. An application specific opt out is also in operation.

The CAG considered that the notification flyer was hidden on the website. This should be made more central and easy to access. The Committee wondered if this flyer was also on display in Trusts or website only. The Members noted that it appears TARN had active social media accounts, for example Twitter.

Regarding the content of the flyer, the CAG considered this to be broadly reasonable, and in a layered fashion as there is a link to the longer privacy notice, but suggested some improvements;

- The CAG noted there is a link to the longer privacy notice on the website, and that partway through the length of the privacy notice it details how a patient can opt out of TARN. However there was no mention on the flyer of the TARN specific opt out mechanism, and the Members felt this should be added to the flyer, in order to show patients clearly how they can opt out of TARN without having to go through to the privacy notice.

- It was noted that it is not clear who the cohort are from the flyer – it should be made clear that TARN collects data regarding certain trauma patients attending Major Trauma receiving Hospitals. Noting it is stated TARN collects 'trauma data' but the cohort should be more clearly specified.

- It was commented that the only means of contact on the flyer is an email address. A phone number should also be provided.

- The role of CAG is described as follows – '*TARN has section 251 approval from CAG to allow us to collect and hold patient data from England or Wales without consent. CAG reference ECC 7-05(g)_2011'.* However there are some inaccuracies in this statement regarding the role of CAG, and the Committee would prefer if this sentence was changed to something more similar to;

  'The Secretary of State for Health and Social Care, on advice from the Confidentiality Advice Group (CAG), an independent body of experts and lay people, has supported TARN, to allow us to collect and hold confidential patient information from England and Wales, without consent under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support')'

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.

There is public representation on the TARN board and the applicant states invitations for further patient and public involvement will be advertised later this year. The committee has had a patient and public involvement member since 2016. Governance and requirements for the use of confidential patient information is discussed by the TARN Board where patient and public representation is present.

The Members considered that although the TARN board does have lay membership, and the TARN board has accepted the use of 's251 support' throughout the length of the previous TARN applications, there appears to be little direct evidence of meaningful discussions surrounding the acceptability of the use of confidential patient information without consent. They also noted that there is mention of the Sheffield Emergency Care Forum, however these discussions appeared to be surrounding PROMs data rather than the use of confidential patient information without consent. The Members considered that the applicant should gather together a group of patients and the public, in the region of 20 or more, either face to face or via electronic methods. The applicant should undertake meaningful patient and public involvement consultations, to ensure the acceptability of the use of confidential patient information without consent in the manner required for the purposes of TARN, and also for feedback on the notification flyer, privacy notice, and any ideas the group may have for other notification methods.

Exit strategy

NHS numbers will be retained for three years and then deleted. This is the same as the current TARN application. Date of birth is retained indefinitely. The members were unclear why this length of duration was required for retention, and further justification is requested, as detailed in the 'justification of identifiers' section above.

Support is required in an ongoing fashion for continuous data collection into TARN. Support is provided for 5 years in the first instance, and a duration amendment will be required at that time to ensure the application continues to fit the current Information Governance processes.

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 Secretary of State for Health and Social Care, 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. ECC 7-05(g)/2011 and PIAG 3-04 (e) 2006 will be expired from the date of this letter, and superseded by 22/CAG/0014. Please note new annual revie date.

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

3. Please provided clear justification as to why NHS number is required to be retained for 3 years, and why date of birth is required to be retained indefinitely. Please provide a response to CAG within three months from the date of this letter.

4. Please ensure the flyer is more visible on the TARN website. Please provide a response to CAG within three months from the date of this letter.

5. Please confirm if the flyer provided is also displayed in clinical areas in Trusts or is this available on the website only? Please provide a response to CAG within three months from the date of this letter.

6. Please make the changes as described in this letter to the notification flyer and provide an updated version to the CAG within three months form the date of this letter. This includes;
    a. Making it clearer how to opt out on the flyer
    b. Explain who the cohort are on the flyer
    c. Include a phone number alongside the email address on the flyer
    d. Ensure the role of CAG is more accurately described

7. Please undertake further patient and public involvement, as described in this letter, and provide a progress report to the CAG within three months form the date of this letter. This includes;
    a. Ensuring 20 or more people are consulted
    b. Ensure the use of confidential patient information without consent is discussed
    c. Ensure the patient notification flyer, privacy notice and any other potential methods are discussed

8. 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 **The Trauma Audit & Research Network (J160), University of Manchester** (re data safe haven storage of HES and ONS data), **NHS Digital, and Quality Health** were confirmed as ‘**Standards Met’** on the NHS Digital DSPT Tracker (checked 18 February 2022)

Department of Health and Care Wales (DHCW) has a Caldicott Principles into Practice (CPiP) Out-turn report with a score of 97.5%, and improvement plan for 20/21 provided 9th June 2021.

Due to the number of participating care providers involved it is the responsibility of TARN, as controller, to ensure that all organisations disclosing confidential patient information to TARN meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

d. 22/CAG/0010 - The Integration and Analysis of Data Using ARtificial InTelligence to Improve Patient Outcomes with Thoracic Diseases

Context

Purpose of application

This application from Oxford University sets out the purpose of medical research that seeks to develop an Artificial Intelligence model to aid in the diagnosis of lung cancer in pulmonary nodules identified on CT scans performed as part of the NHSE Lung Cancer Screening Programme.

Lung cancer is the most lethal and second commonest cancer in the UK. Lung cancer is also the commonest cancer worldwide, with 1.8 million cases diagnosed each year. Early diagnosis can reduce mortality, however early diagnosis is dependent on both the detection of a lung nodule and the determination of whether this is malignant. CT scanning has been shown to be a useful method of detecting lung nodules as part of a lung cancer screening programme, determining whether a nodule is benign or malignant is challenging. Lung nodules are detected in around 25% of scans carried as part of routine care or in lung cancer screening trials for smokers. Approximately 98% of these nodules are benign, meaning that large numbers of patients have pulmonary

nodules detected on their scans which are not of significance but result in significant patient anxiety, and also places a substantial burden on scanning facilities and staff. The applicants seek to create a CT AI model which will produce a percentage likelihood of malignancy and a follow up algorithm, calculating how many CT scans are required and the interval needed. CT scan images will be overlaid with images gained from digital pathology scanning, to aid in interpretation of the CT image. The applicants hypothesise that further characterisation of pulmonary nodules on chest CT scans and histology specimens will improve the accuracy of stratifying lung nodules as benign or malignant and help guide their management.

Participating NHS trusts will transfer clinical data, including patient NHS numbers, CT images and data, NHS England Lung Health Check Screening spreadsheets and pathology data on a quarterly basis to an NHS DART email account at Oxford University Hospitals NHS Foundation Trust (OUH NHS FT). The data will then be pseudonymised and transferred to the Trust Hermes Research server. Histology slides, from biopsies and lung resections, will be transferred after the patients' care has been completed. The patient identifier will be taped over, and a pseudonymisation number given to the slides. The slides will then be posted to the Tissue Histopathology Laboratory (THL) in Oxford, where they will be digitised and then posted back to the originating laboratory. The digital images from the THL will then be transferred to the Radiology Research Laboratory in the OUH NHS FT, and the pseudonymised slide will then be linked to the code from the originating laboratory, and the images then pseudonymised and transferred to the research server at OUH NHS FT. The data can then be transferred to researchers for the Dart project at the University of Oxford, Roche, GE and Optellum. The dataset will be effectively anonymised at this point, as the researchers will not be able to link the dataset to the patients NHS numbers.

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

Confidential patient information requested

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

Cohort	All patients invited for a Lung Health Check within England from 01 January 2019 onwards. Those aged between 55 and 80 years are invited for Lung Health Checks.

	It is estimated that 300,000 patients will be included.
Data sources	1. Patient records at the Lung Health Check centres 2. Patient records from the referral hospitals 3. Pathology data 4. Radiology data
Identifiers required for linkage purposes	1. NHS number
Identifiers required for analysis purposes	No items of confidential patient information will be retained for analysis purposes

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

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application had a medical purpose and was 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 applicants advised that consent was not feasible due to the potential size of the cohort, 300,000 patients recruited from four Lung Health Check centres. Many scans will have taken place in previous years. The CAG agreed that seeking consent from patients recruited retrospectively was not feasible. Members asked the applications to consider whether consent could be sought from patients recruited prospectively. If it was determined that consent could not be sought from the prospective cohort, further justification on why not needed to be provided.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link data from various sources, including the patient record system, radiology reports, Lung Health Check data and pathology reports to Oxford University Hospitals NHS Foundation Trust (OUH NHS FT). This cannot be undertaken in any other way.

The CAG requested clarification on who outside of the direct care team would have access to confidential patient information.

'Patient Notification' and mechanism for managing dissent

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

The applicants provided a privacy notice and poster. The poster advises patients to contact the DART team at OUH NHS FT or to contact their local team. The poster will be customised with local contact details and displayed in each Lung Health Check waiting room, or similar if on a mobile unit. It will also be displayed at the waiting reception area of each follow-on procedure. The one-page information sheet will be available for patients to pick up at the LHC. The LHC will have longer sheets printed/available on request. The poster and both information sheets can both be viewed or downloaded from the DART website. The Privacy Notice will be available at each LHC.

The National Data Opt-Out will be applied automatically to all received data on behalf of the participating trusts. The applicants plan to maintain and update an active list of NHS and hospital numbers (MRNs) of opted out patients from participating centres

throughout the data collection period. This will be deleted as described in the exit strategy section below.

The CAG agreed that revisions to the patient notification materials were required. The Information Sheet and Privacy Notice were not very patient-friendly and required restructuring to be more accessible.

The patient notification materials needed to explain how the National Data Opt-Out and project-specific opt-outs would be applied, including who would apply them. An explanation of the commercial partners involved and their role also needed to be included.

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 lay representative from the Roy Castle Lung Cancer Foundation has reviewed the protocol and privacy notice. The representative also attends the DART Quarterly Review Meetings. The use of patient identifiable data has also been discussed at the monthly LHC centre meeting.

The applicants noted that they would be responsive to suggestions of how the website, poster and information sheets could be updated.

Exit strategy

The applicants advised that, once the data collection has ended and the final linkage, opt-out check and quality assurance checks have taken place, the patient identifiers used to conduct the linkage will be deleted.

Once the applicants are satisfied that they have extracted as much value as possible from the raw data stores, these will also be deleted, leaving a master copy of all sharable, anonymised information from which suitable extracts for any additional collaborations can be prepared.

The answer to Q48 stated that “Once pseudonymised the identifiers will be held in a separate database, on a separate password protected computer. This separation will happen immediately on pseudonymisation.” The applicants clarified that this process had been revised since the application was submitted. Primary identifiers will be maintained in a separate schema and will be accessible only by developers with

honorary OUH contracts and the automatic processes that operate on the data archive and newly arrived radiology images. However, it may be necessary for an NHS contracted member of data management staff to manually create Image Exchange Portal (IEP) requests for images and reports about patients listed in the NHSE LHC Spreadsheets for some centres. The applicants are working with Sectra, the IEP supplier, on an interface so that they will be able to automatically generate these requests.

The applicants confirmed that Oxford University will have no access to linkage information or confidential patient information at any stage in the project.

The CAG agreed that further patient and public involvement needed to be carried out. This needed to include discussion of the specific issue of use of confidential patient information without consent as proposed in the application and the involvement of commercial partners.

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. Clarify who outside the direct care team will have access to confidential patient information.

2. Consider whether consent could be sought from patients in the prospective cohort. If it was determined that consent could not be sought from the prospective cohort, further justification on why not needs to be provided.

3. The following changes to the patient notification materials are required:

    a. Clarification on the role and nature of the relationship with the commercial partners in the project needs to be included.

    b. The Information Sheet and Privacy Notice need to be restructured to be more patient friendly.

c. An explanation on who would apply the National Data Opt-Out and the project specific opt-out needs to be provided.

4. Further patient and public involvement needs to be carried out, including discussion of the specific issue of use of confidential patient information without consent as proposed in the application and the involvement of commercial partners.

5. The above conditions need to be responded to within 3 months of the issuing of this outcome letter.

6. Favourable opinion from a Research Ethics Committee. **Confirmed 07 December 2021.**

7. 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 Oxford University Hospitals NHS Foundation Trust – and Oxford University were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 20 February 2022)

Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.

e. 22/CAG/0012 - Evaluating opioid use and safety in new users using linked EHRs

Context

Purpose of application

This application from the University of Manchester set out the purpose of medical research that seeks to evaluate the prescribing patterns of opioids started in secondary care and continued between intermediate and primary care, in order to provide a better

understanding of prescribing factors and patient subgroups at a high risk of opioid related harms.

Opioids are commonly prescribed to patients for the first time for a number of reasons, including following surgery. Patients undergoing orthopaedic surgery for musculoskeletal conditions, such as osteoarthritis, are a particularly vulnerable population for opioid-related harms due to older age, multi-morbidity and polypharmacy. Clear postsurgical opioid prescribing is not currently available, partially due to limited evidence about current prescribing patterns in hospital and post-discharge, and the subsequent effect of longer schedules of post-discharge opioids.

Patients will be identified from the EHR records for all adult patients registered with Salford Royal NHS Foundation Trust (SRFT). Prescription and other electronic data will be used to identify all those who have been given opioids during an in-patient stay since 2009. This will be done by the Salford Business Intelligence Team, who have experience with performing and extracting such information for similar studies. Only the Salford Business Intelligence team will have access to the NHS numbers required to link the data sources. No items of confidential patient information will leave the Trust or be accessible to the researchers. Support is needed as, while the Business Intelligence Team at the Northern Care Alliance (NCA) access secondary care data routinely for planning and research, they do not usually access the primary care (SIR) dataset. CAG support is requested to provide a legal basis for access to the SIR dataset and for the BI team to retain the hashed algorithm until the end of the study. The de-identified dataset which is then made available to UoM researchers in a project-specific space in NCA datalake.

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

Confidential patient information requested

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

Cohort	Patients aged 18 years and over admitted to Salford Royal NHS Foundation Trust between 01 January 2010 and 31 August 2021, who were receiving an administered opioid medication.

	The applicants estimate that 50,000 patients will be included.
Data sources	1. Salford Integrated Record (SIR), primary care data
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID number 4. Date of birth
Identifiers required for analysis purposes	1. Postcode – district level 2. Gender 3. Ethnicity

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.

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 advised that consent was not feasible due to the size of the cohort. The CAG agreed that consent was not practicable.

- **Use of anonymised/pseudonymised data**

The applicants require access to confidential patient information to undertake the data linkages. This cannot be undertaken in any other way.

'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.

Patient notifications will be placed in SRFT clinics and on relevant NCA websites as part of the wider Jigsaw programme. The notification will contain contact details. The patient notification document was provided. Patients who wish to opt-out will be advised to email a member of the BI team at NCA with their name, date of birth and address. The NCA will apply the National Data Opt-Out.

The CAG asked that the patient notification poster was provided for review. All patient notification documents needed to include postal and telephone contact details, as well as email, for patients to register dissent.

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 they had presented the programme of work on opioid use and safety to the Research User Group (RUG) at the Centre for Epidemiology Versus Arthritis. Feedback was also sought from the Virtual Rug, a separate group of 30 individuals who provide feedback via email. A patient partner is also involved in the project.

As part of a larger programme of work funded by the Nuffield Foundation (Assembling the Data Jigsaw), a dedicated PPI Working Group will play a key role in developing a Communications and Engagement Strategy, in conjunction with the SRFT and Salford

Communications team. This strategy will proactively seek to establish effective two-way communication with patients, carers, the public and other stakeholders across the Salford area.

The CAG agreed that further patient and public involvement needed to be carried out. This further involvement needed to include engagement with patients who have been prescribed opioids.

Exit strategy

The research team will receive a de-identified dataset only.

The NCA will retain a de-identified copy of the dataset and the pseudonymisation key (the hashing algorithm), so NCA staff will be able to re-identify the dataset. The dataset will be retained for 10 years on behalf of the University of Manchester.

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. Further patient and public involvement, including engagement with patients who have been prescribed opioids, needs to be carried out and feedback provided to the CAG within 3 months of the issuing of this outcome letter.

2. The patient notification poster needs to be provided for review within 3 months of the issuing of this outcome letter.

3. Confirmation needs to be provided that all patient notification documents will include postal and telephone contact details, as well as email, for patients to register dissent. This confirmation needs to be provided within 3 months of the issuing of this outcome letter.

4. Favourable opinion from a Research Ethics Committee. **Confirmed 17 January 2022.**

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

   The NHS Digital **2020/21** DSPT reviews for **the University of Manchester and the Northern Care Alliance** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 February 2022).

4. Any other business

No other business was raised.

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

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date 04/04/2022
Dr Tony Calland		
Professor Will Bernal		
Signed – Confidentiality Advice Team		Date 04/04/2022
Kathleen Cassidy		