Minutes of the meeting of the Confidentiality Advisory Group

16 June 2022

Held via Zoom

Present:

Name	
Dr Tony Calland MBE	CAG Chair
Professor William Bernal	CAG alternative vice-chair
Dr Sandra Duggan	CAG member
Dr Rachel Knowles	CAG member
Dr Pauline Lyseight-Jones	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Ms Diana Robbins	CAG member
Mr Dan Roulstone	CAG member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Michael Pate	HRA Confidentiality Advisor
Sarah Oyebanjo	NEIAA Project Manager (Item 3a only)
James Galloway	NEIAA Lead Methodologist (Item 3a only)
Professor Rory Collins	Chief Investigator – attended to answer queries about 22/CAG/0090 (item 4a only)
Michelle T Nunn	Clinical Trial Manager – attended to answer queries about 22/CAG/0090 (item 4a only)

1. Introduction, apologies and declarations of interest

CAG Members Dr Katie Harron and Professor Lorna Fraser gave apologies.

No conflicts of interest were declared.

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 agreed with the advice provided by the CAG in relation to the **12 May 2022** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **12 May 2022** meeting applications.

3. Consideration items - requests for National Data Opt-Out exemption

a. 18/CAG/0063 - National Clinical Audit of Rheumatoid and Early Inflammatory Arthritis Clinical Audit

NEIAA has been supported since 2018, with consistent submission of annual reviews since that time. Support is in place for clinical teams to provide the audit team with confidential patient information, which is linked with datasets held by NHS Digital and the Office for National Statistics.

The applicants provided a supporting paper, which set out the rationale given for making the request to defer application of the National Data Opt-Out.

Confidentiality Advisory Group advice

1. Deferral rationale: Patient safety

Over 50,000 patients have been recruited to NEIAA, making it the largest outpatient database of patients with inflammatory arthritis. Data produced by the NEIAA has shown that there is significant geographical variation in care provided to patients with inflammatory arthritis. The availability of organisational, process and outcome measures collected by NEIAA allows services and commissioners to identify areas that require improvement and thus reduce mortality and morbidity through improved quality of care.

As the NEIAA collects data in near real time, trusts are provided with information on what is happening within their trust and use this data to drive quality improvement.

The CQC also used information from NEIAA to promote patient safety and inform their surveillance approach. The real time data analysis reports produced by NEIAA may also be used by the CQC when contacting trusts to query recent trends. The CQC rely on high levels of data completeness and case ascertainment reporting. If the NEIAA data reduced in completeness and, if the NEIAA data reduced in completeness or was significantly biased, the CQC may then use their own legal powers to ask trusts to submit cases excluded by implementation of the National Data Opt-Out. This would lead to duplication of data entry for the trusts and potential confusion if the NEIAA and the CQC cannot operate on the same dataset.

2. Deferral rationale: Introduction of bias

Women and those aged between 30 and 60 years of age are disproportionately affected by EIA. These groups are also disproportionately represented in the National Data Opt-Out. There were also geographical factors in application of the National Data Opt-out and, in some GP practices 75% of patients had opted-out.

Each trust needed to have a minimum of 20 patients in order to be included. Application of the National Data Opt-Out may mean that some trusts fall below that number and would drop out of the audit. The applicants had identified 12 trusts that would drop out.

The NEIAA was established to provide complete and unbiased information to patients, the public, hospitals, commissioners and regulators. The potential consequences from these non-random opt out patterns is that the quality of information collected will be reduced, leading to centres being incorrectly identified as outliers or the non-identification of centres that were performing poorly. There is a risk that this will increase health inequalities.

3. Deferral rationale: Technical impacts

Requiring trusts to check the National Data Opt-Out before registering each patient would place an administrative burden on the participating trusts. Asking trusts to amend the way data was collected would also increase the administrative burden. Trusts struggling to provide good care, who consequently were most in need of monitoring, were also likely to struggle with any additional burden. The difficulty faced by trusts that had not established a method of applying the National Data Opt-Out was not sufficient justification alone to defer application of the Opt-Out. However, the CAG recognised that, in this specific application the loss of struggling trusts to manage the technical aspects does influence health inequalities if they are consequently not included in the audit.

Informing the patient population

The applicants provided a supporting paper. This paper set out a summary of the patient notification routes. A separate communications strategy document was also provided, alongside a range of patient notification materials.

The supporting paper did not reference a local opt-out, however the applicants had advised in a separate communication that a local opt-out was available.

The patient notification materials did not explain how it was decided that the National Data Opt-Out would not be applied and CAG asked that this was included.

The CAG also asked that all the local opt-out notification materials contained a contact name and telephone, email and postal contacts.

Confidentiality Advisory Group advice conclusion

Members noted that there was not a risk to patients' life should a small amount of data be lost from the audit and queried whether the patient safety argument was strong enough to outweigh the need to respect the National Data Opt-Out. The CAG noted that minimising harm to patients was not limited to avoiding death, but also other impacts such as late diagnosis.

The CAG agreed that a compelling argument for deferring application of the NDOO would be use of data to address health inequalities.

If the National Data Opt-Out was applied, then less-organised units and those who treated smaller numbers of patients may drop out of the audit and their data would be lost. This may mean that entire trusts were unable to participate in the audit.

The CAG agreed that further statistical information was required to demonstrate the adverse impact that application of the National Data Opt-Out would have, especially regarding health inequalities, so evidence long-term deferral. Members asked that the applicants undertook modelling, comparing England with Wales, as no National Data Opt-Out is applied in Wales, to evidence the potential impact of the National Data Opt-Out on the audit. Feedback from this modelling was to be provided within 6 months of the issuing of this outcome letter. The CAG would then determine whether support should be recommended for a longer-term deferral of the National Data Opt-Out.

The CAG agreed that they were supportive, in this specific instance, of the request for the application of the National Data Opt-Out to be disapplied in relation to the non-research activities contained within 18/CAG/0063. The CAG therefore recommended to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request was conditionally supported for 6 months.

Specific conditions of support

1. Modelling, comparing England with Wales, as no National Data Opt-Out is applied in Wales, to evidence the potential impact of the National Data Opt-

Out on the audit is to be carried out. Feedback from this modelling is to be provided within 6 months of the issuing of this outcome letter

2. The patient notification materials need to be revised as follows:
    a. An explanation on how it was decided that the National Data Opt-Out would not be applied needs to be included.
    b. All local opt-out notification materials need to contain a contact name and telephone, email and postal contacts.
3. The National Data Opt-Out is not to be applied to patients included in the activities specified in 18/CAG/0063.
4. A local patient objection mechanism must continue to be used in relation to 18/CAG0063.

4. New applications – SDDR Pilot

a. 22/CAG/0090 - ISIS 2 Legacy database

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research that seeks to continue analysis of confidential patient information collected for the ISIS-2 trial, which was initiated in 1985 to explore treatment of acute heart attack.

Recruitment for the ISIS-2 main trial took place in hospitals between March 1985 and December 1987. 6,213 patients were recruited within the UK. The study population was patients who had suffered an acute heart attack. Participants were randomised to receive either intravenous streptokinase or a matching placebo, plus oral aspirin or a matching placebo. After recruitment ended in December 2981, the ISIS-2 study team continued to collect medical information held by UK Central Registries, such as the Office for National Statistics (ONS), until 1997. The findings from the ISIS-2 trial were that patients taking streptokinase and/or aspirin were more likely to survive than those taking the placebo and the benefit seem to last for at least 10 years.

Support currrently is only requested for the continued holding of confidential patient information collected during ISIS-2. The applicants are reapplying to CAG as, while some of the data collected is part of the applicants' Data Sharing Agreement with NHS Digital, after discussion with NHS Digital it was determined that the original

consent was not sufficient and that previous Section 251 support had expired. Although the applicants only seek to continue to hold the confidential patient information and have no current plans for further data linkages or research, the applicants note that the data collected may be used to undertake research in future, such as subgroup analysis and long-term data linkage. The applicants also noted that, while the original trial was conducted several years ago, ISIS-2 remains one of the few trials to demonstrate the benefits and safety of treatment with streptokinase. It is also the only trial that has demonstrated the benefit of aspirin in the setting of acute heart attack.

The applicants advised that amendments will be submitted should confidential patient information collected for ISIS-2 be used to undertake data linkages and/or further research in the future.

Confidential patient information requested

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

Cohort	The ISIS-2 cohort were recruited between March 1985 and December 1987. 6,213 participants were randomised into the trial in hospitals in the UK. 4666 patients were recruited within England and Wales. Patients had had an acute heart attack (MI) and were a median age of 60-69 years old at randomisation.
Data sources	1. Data collected for the ISIS-2 Trial, held at University of Oxford (Nuffield Department of Population Health)
Identifiers required for linkage purposes	1. NHS number 2. Name 3. Address 4. Date of birth

	5. Postcode 6. Gender
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Gender
Additional information	Date of death, date of birth and gender will be kept within the main trial database to retain the usefulness of the dataset. All other identifiers will be stored separately.

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 original study had a medical purpose and was in the public interest, and that there was a public interest in holding an anonymised dataset. However, the public interest and medical purpose in continuing to hold the confidential patient information in the dataset was less clear.

The CAG noted that no research using the dataset appeared to have taken place since 1998 and the dataset last updated in 2014. Around 95% of patients were now deceased and there was a lack of clarity over the potential further data linkages that could be carried out using the data. It was also unclear whether any specific uses for the data were planned.

The CAG noted that the applicants had no plans for any further data linkages and queried whether the database was publicised to other researchers. The applicants advised that the Nuffield Department of Population Health made it clear to the research community that they held databases for use in research, but did not advertise this database specifically.

The CAG agreed that it was not in the public interest to retain the identifiable dataset indefinitely. Members determined that the applicants should be given one year to undertake data linkages to bring the dataset up to date and collect any useful follow-up information. After that year, the dataset would need to be anonymised.

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**

Participants in the study are patients who had experienced an acute heart attack. Patients were recruited between 1985 and 1987 and were aged between 60 and 69 years at the time. Most participants are now deceased and cannot be recontacted for up-to-date consent.

A small number of participants are still living; however, the applicants seek to minimise the burden and distress caused to participants. Participants also may lack capacity.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required in order to permit future data linkages and to retain the usefulness of the existing database.

The applicants also noted that the study data was stored on a computer operating system that was no longer used. Updating the dataset to convert the data to less identifiable variables would require significant time and resources. The CAG noted that the dataset would need to be updated to a current computer operating system so the dataset to be used to carry out further data linkages. Members determined that either the dataset was worth committing the resources to updating so it could be used for further data linkages, or it was not.

Patient notification and 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 made available on the study website. An email and postal address were included. The applicants were asked to include a telephone number. They have agreed to this but advised that the revised Privacy Notice will be provided after the joint status update is issued from REC/CAG. The applicants provided the ISIS-2 Lay Text for website.

The Privacy Notice advises patients to contact the NDPH study team to withdraw consent. This will be applied to the files being held for data linkage and to any future work that might be done. It is not possible to remove patient information from analyses that have already taken place. No further data is being requested from NHS Digital. The CAG raised no queries under this heading.

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.

Participants in clinical trials are involved in the Patient & Public Involvement (PPI) panel. This ISIS-2 specific PPI group is a sub-group of the Oxford Population Health Public Advisory Group. Some members have been involved in cardiovascular trials and others have been involved in trials that use ongoing data linkage.

Participants from the sub-group were provided with a lay summary about the ISIS-2 trial prior to an online meeting. During the meeting, they were given a presentation that described the original trial, and why the applicants seek to keep the data (including issues around consent and patient identifiers). NDPH then asked for their opinions both for this sort of work in general and specifically around retaining participant identifiers for the purpose described in the application.

The applicants noted that they would carry out further patient and public involvement should the confidential patient information collected be used for research in the future. The CAG raised no queries under this heading.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. The dataset is to be retained in an identifiable format for 12 months following the issue of this outcome letter. After 12 months, the dataset is to be anonymised and all items of confidential patient information deleted.

5. New applications – COPI transition

22/CAG/0097 - AGILE: Seamless Phase I/IIa Platform for the Rapid Evaluation of Candidates for COVID-19 treatment

Context

Purpose of application

This application from the University of Southampton (with the joint controllers for the activity confirmed to be the University of Southampton and the University of Liverpool) set out the purpose of medical research which aims to allows incorporation of new potential treatments (candidates) that either only have laboratory data or limited patient data to indicate they may work to treat COVID-19. This early phase platform will look closely at dose, safety and evidence that they work before entering these other large phase trials.

Research sites have received data for COVID positive patients from GP practice surgeries, local and supra-regional testing laboratories (Pillar 1 and 2) and local CCGs under the COPI Notice and this has been used to identify and approach potential patients to see if they are interested to participate, and consent is gained if they agree. Under Regulation 5, this, and potentially data from other organisations listed below, are still required for Candidate-Specific Trial 5 (CST-5) that is recruiting COVID positive patients and for future CSTs to recruit COVID positive patients. CST-5 has recruited 36 patients out of a target figure of 149.

Support is requested to allow the disclosure of confidential patient information from UKHSA, GP practices, local public health authorities, and local CCGs, to site research teams for those research teams to approach potential participants by phone and take their consent. The identification, approaching and recruitment of COVID positive patients is ongoing for CST-5 now and will be starting for future CSTs.

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	Patients aged 18 yrs and above with laboratory-confirmed (PCR) SARS-CoV-2 infection. (actual number contacted to date and the number of records to be accessed post-COPI is unknown)
Data sources	GP surgeries (England and Wales) Patient medical records UKHSA (England only) Pillar 1 (daily) and Pillar 2 (weekly) testing data Local Public Health Authorities (England and Wales) Local Clinical Commissioning Groups (England and Wales)

Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Telephone number
Identifiers required for analysis purposes	1. None as identifiers will only be kept with consent.
Additional information	The CAG form indicates NHS Digital as a potential source of CPI; however, this has not yet been agreed, so it is proposed that NHS Digital are added as a data source via an amendment, should that be necessary.

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.

Scope

The CAG noted that the application is currently relying on an alternative legal basis to process confidential patient information without consent, under the 'COPI notice' and that this will continue for its duration. The group therefore considered the elements of the project that are expected to be continuing following expiry of the 'COPI notice', and which require support under regulation 5.

Support is requested to allow the disclosure of confidential patient information from UKHSA, GP practices, local public health authorities, and local CCGs, to site research teams for those research teams to approach potential participants by phone and take their consent. The identification, approaching and recruitment of COVID positive patients is ongoing for CST-5 now and will be starting for future CSTs.

Sites will be provided with the gender and year of birth of people to ensure that they are contacted a maximum of 3 times. However, this is not CPI and thus the flow of this data does not fall under the scope of support.

The CAG form states that the study will take place in all 4 countries of the UK. CAG support will only extend to sites in England and Wales.

The CAG was not clear on the number of patient records that would be provided by each organisation transferring CPI and would like confirmation of this.

The CAG would like confirmation of the data sources being used by each organisation to provide the appropriate details of those that meet the inclusion criteria to the research teams.

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 was content that the request for Regulation 5 support 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 applicant has explained that the recruitment method for each CST can vary significantly. In order to approach as many people as possible belonging to the cohort in each CST, research sites need to receive identifiable information of potential participants from multiple data sources.

Subject to clarification on the points above with respect to data sources and the number of records being transferred, the CAG accepted that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Site staff could not use pseudonymised data, as they have to know the person's name and telephone number in order to approach them to take part in the study.

The CAG accepted this explanation.

'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 AGILE Data Privacy Notice is soon to be finalised and sent to the UKHSA for approval, prior to being uploaded and visible to the general public on the AGILE website.

The organisations providing data to the research sites should have a process to ensure that they do not provide data for a patient if they have opted out in the National Data Opt-Out. If a research site is contacted by the National Data Opt-Out, informing them that a patient on a list provided has opted out on the National Data Opt-Out, the site will update the data stored for this patient and not contact them from that time forwards.

If a patient has 'opted out', their details will not appear on the electronic lists that are provided by the following:

- General practice surgeries
- Local and supra-regional testing laboratories (Pillar 1 and 2)
- Local Clinical Commissioning Groups (CCGs)
- Local Public Health and local authority testing facilities

- Local Public Health Authorities
- UKHSA System

If a potential patient declines to take part in the study this will be documented on a password protected document stored on a secure server and they will not be contacted again. In order to avoid further contact, this document is checked prior to contacting potential patients on future lists.

Site research teams will try to contact a potential patient by phone; this will be a maximum of 3 times. If there is no response, the patient will not be contacted again in the future for the study. When contacted by the site research team by phone, if a potential patient declines to take part in the study, this will be documented on a password protected document stored on a secure server and they will not be contacted again. Initials, year of birth and gender are documented to identify the patient to ensure that they are not contacted again if they declined. In order to avoid further contact, this document is checked prior to making contact with potential patients on future lists. A patient can withdraw from the study at any time by contacting the local site research team.

The CAG felt that the website was difficult to find and that the privacy notice did not contain much detail about the collection of participant CPI. It was felt that the privacy notice needed to be clearer to participants.

Given the number of organisations from which data is being received, and the scale of the overall study, the CAG would like the applicant to confirm whether, other than the AGILE website, there will be any other notification channels and what these routes are.

The CAG would like to know whether participants are told about the storage of their data, even where it is non-identifiable, prior to them consenting or declining to the study.

The CAG would like details about how each organisation involved in the study would invoke the National Data Opt-Out, or a local opt-out, and how this would be managed.

The CAG would like the privacy notice to be rewritten to be clearer about what Regulation 5 support will be covering, to include details of the opt-out mechanisms available to participants. This should be done within 3 months of the date of the conditional outcome.

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.

Since 5 April 2022, the AGILE PPI Group has been meeting to discuss and review any AGILE related matters. This will continue. As well as discussing AGILE related matters they are also available to review and comment on study related documentation, such as: protocols, PIS, ICF, DPN, advertisement posters, GP Letters.

The applicant has confirmed that, within the next 3 months, the PPI group will discuss the acceptability of using confidential patient information without consent.

The CAG would like confirmation that, within 3 months of the conditional outcome, the PPI group has reviewed the privacy notice for acceptability and has also discussed the acceptability of using confidential patient information without consent. Details of the demographics of the group, including what was discussed and the views of the group should be provided in response.

Exit strategy

Once contact of potential participants is made and consent is taken, support will no longer be required, as participants will be proceeding on a consented basis.

Where potential participants decline to take part in the study, or do not respond after 3 attempts at contact, their CPI will be destroyed. Only initials, year of birth, gender and

outcome of contact (non-identifiable data) will be stored for 30 years. Support will therefore end at this point for those potential participants.

The CAG felt that participants who decline to take part should have the option to decide whether their data is stored or destroyed, even though it is not identifiable. Please confirm that you will give participants this option and how this will be done.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, **prior to expiry of the COPI Notice.**

Request for further information

1. **Please clarify the number of patient records that would be provided by each organisation transferring confidential patient information (CPI)**

2. **Please confirm the data sources being used by each organisation to provide the appropriate details of those that meet the inclusion criteria to the research teams.**

3. **Please confirm whether, other than the AGILE website, there will be any other notification channels and what these routes are.**

4. **Please clarify whether participants are told about the storage of their data, even where it is non-identifiable, prior to them consenting or declining to the study.**

5. **Please provide details about how each organisation involved in the study would invoke the National Data Opt-Out, or a local opt-out, and how this would be managed.**

6. **The CAG felt that participants who decline to take part should have the option to decide whether their data is stored or destroyed, even though it is not identifiable. Please confirm that you will give participants this option and how this will be done.**

Specific conditions of support

The following sets out the specific conditions of support.

1. Within 3 months of the date of conditional support, confirmation that the PPI group has reviewed the privacy notice for acceptability and has also discussed the acceptability of using confidential patient information without consent. Details of the demographics of the group, including what was discussed and the views of the group should be provided in response.

2. Within 3 months of the date of conditional support, to provide a revised privacy notice to be clearer about what Regulation 5 support will be covering, and to include details of the opt-out mechanisms available to participants.

3. Favourable opinion from a Research Ethics Committee. **Confirmed 12 May 2020**

4. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The applicant must ensure that NHS Digital confirmation of 'standards met' for organisations processing confidential patient information (GP surgeries, local Public Health Authorities, UKHSA and local Clinical Commissioning Groups and their successors, the Liverpool University Hospital NHS Foundation Trust, the University Hospitals Southampton NHS Foundation Trust and King's College Hospital NHS Foundation Trust) is in place once support under Regulation 5 is active.** See below for further details.

Security assurance requirements

It is a policy position of the Department of Health and Social Care that all bodies that process patient information in England under Regulation 5 have their DSPT submissions reviewed by NHS Digital to provide assurances that the DSPT self-assessed submission has achieved the appropriate 'standards met' status. Similar

policy positions apply when the processing is undertaken within the devolved nations.

As such each applicant, **no less than 4 weeks prior to expiry of the COPI notice**, should ensure that all organisations that will be processing confidential patient information without consent under this support have the necessary assurances in place. Full guidance on how to request these assurances, depending on which nation the organisation lies can be found on the HRA website. For further information please contact the Confidentiality Advice Team.

6. Resubmitted applications – Research

22/CAG/0086- The Norfolk Arthritis Register (NOAR)

Context

Purpose of application

This application from the University of East Anglia set out the purpose of medical research that continues the Norfolk Arthritis Register (NOAR), which investigates and identifies the genetic and non-genetic factors which may be related to the onset of inflammatory arthritis, response to treatment and its 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 undertake 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.

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
Additional information	

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.

Scope

The applicants had advised that there are approximately 3,058 participants whose consent does not cover the linkage for mortality data and 2,777 participants whose consent does not cover the linkage for HES data. The applicants advised that re-consenting these participants would not be practicable due to the possibility of non-response and that the exclusion of non-responders would significantly undermine the scientific integrity of the project.

The CAG agreed that the queries raised in the previous deferred outcome letter had been adequately addressed, other than the question on why patients who did not respond to contact needed to be included. The CAG requested that further justification was provided as to why non-responders needed to be included.

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 they had discussed this issue 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. The CAG raised no queries under this heading.

- **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. The CAG raised no queries under this heading.

‘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 privacy notice is displayed on a dedicated page of the Register’s website. 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 to make a request 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 raised no queries under this heading.

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 have maintained close involvement with patient groups throughout the NOAR project. NOAR has 26 active and engaged participants on their PPIE panel. The 26 members of the panel contribute and attend various meetings/comment on various materials.

The CAG noted the information given regarding patient and public involvement and engagement, and raised no further queries.

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. The s251 support will provide an ongoing legal basis for anyone who is deceased, lost to follow up, and patients whose follow up is complete and are no longer in touch with the study. The CAG raised no queries under this heading.

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. Further justification is requested as to why non-responders need to be included.

Specific conditions of support (provisional)

1. Favourable opinion from a Research Ethics Committee. **Confirmed:** 30 April 2015.

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

   Confirmed:

   The NHS Digital **2020/21** DSPT reviews for **University of Manchester, University of East Anglia, and Norfolk and Waveney CCG** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 20 June 2022).

   Pending: The NHS Digital 2020/21 DSPT review for Norfolk and Norwich University Hospital NHS Foundation Trust is pending.

7. New applications – Research

22/CAG/0088 – Evaluating ICON: A mixed methods study to assess the impact of the ICON programme on coping strategies for carers of crying babies, and rates of abusive head trauma in infants aged under one year

Context

Purpose of application

This application from University Hospitals Bristol and Weston NHS Foundation Trust set out the purpose of medical research to evaluate the effectiveness of the ICON programme in reducing incidence of abusive head trauma (AHT) in young infants.

Abusive Head Trauma (AHT) is an injury to the skull or intracranial contents of an infant or young child due to inflicted blunt impact and/or violent shaking. AHT is the most common abusive injury in young children, and occurs most frequently in children under 12 months of age, with an incidence of 20-24 per 100,000 infants per year in the UK. Alongside the physical and emotional consequences for children and their families, AHT is also associated with large lifetime costs from both healthcare and wider societal perspectives. Societal stressors, which include financial recession or natural disasters, are associated with increased AHT rates. However, the most strongly reported association has been with the peak of normal infant crying, a pattern of rising intensity and duration of crying which peaks at 5-6 weeks of age and subsequently settles in an otherwise well infant. Several programmes providing education and support to families have been designed in an attempt to change infant/caregiver interaction, with the aim of reducing incidences of AHT. Whilst early evaluations demonstrated effectiveness of programmes in reducing rates of AHT, this has not subsequently been replicated. However, studies consistently demonstrate numerous other positive outcomes, including increased knowledge and changed response behaviours to normal infant crying, increased seeking of support, and reductions in Emergency Department attendances.

The ICON programme was developed for implementation in the UK. This programme consisted of four simple messages for parents which highlighted the normality of infant crying, suggested that they attempted to comfort the infant, taking a short time away if frustrated, and to never shake the baby. These messages were reinforced during five key touchpoints with health professionals, including antenatally, after delivery, in the

community, and in primary care. Additional innovative and suggested touchpoints include social media, accessing high school children, and at every planned or unplanned contact with healthcare, including Emergency Departments.

The ICON programme has been rolled out to a number of regions since its inception, and a post-implementation evaluation from one of these localities has identified a number of positive impacts. On recognising the likely significant societal stress as a consequence of the COVID-19 pandemic, the ICON programme was implemented by NHS England as a single touchpoint tool across all English maternity units in March 2020. An initial survey-based evaluation of this implementation demonstrated good uptake but also identified a number of challenges, especially in accessing male partners. The applicants seek to build on this and other ongoing work to deliver a mixed methods evaluation study.

Two qualitative studies will be conducted, involving interviews with the parents/carers of children with AHT and interviews with professionals involved in implementing or delivering the ICON messages. These studies are outside the scope of support. Support is needed for a quantitative study. Holders of relevant national datasets, including Hospital Episode Statistics Admitted Patient Care, Emergency Care and Diagnostic Imaging Datasets, the Trauma and Audit Research Network (TARN) dataset, the National Child Mortality Database (NCMD), and the Paediatric Intensive Care Audit Network (PICANet), will identify patients with AHT. Confidential patient information for patients meeting the inclusion criteria will be disclosed to NHS Digital. NHS Digital will undertake linkage and disclose pseudonymised data to the research team at University Hospitals Bristol and Weston NHS Foundation Trust. NHS Digital will retain the linkage key, therefore the pseudonymised data provided to the research team will be effectively anonymised.

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

Confidential patient information requested

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

Cohort	Qualitative; parents/carers - (i) male and female carers aged 18 years or older, (ii) received ICON messages at least once before the baby was eight weeks old, (iii) timeline from delivery to interview of 2-6 months Qualitative; professionals - those eligible will be responsible for commissioning, implementing, or delivering the ICON messages. Quantitative: patients aged up to 364 days who were diagnosed with AHT between 01 January 2016 and 31 December 2021.
Data sources	1. Hospital Episode Statistics Admitted Patient Care, NHS Digital 2. Emergency Care and Diagnostic Imaging Datasets, NHS England 3. The National Child Mortality Database (NCMD), University of Bristol 4. The Trauma & Audit Research Network (TARN) dataset, Northern Care Alliance NHS Foundation Trust 5. PICANet, Universities of Leeds and Leicester
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – district level 3. Gender 4. 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.

Scope & cohort size
The size of the cohort involved was unclear. Members noted that the information given on patient and public involvement cited that the PPI Panel decision was influenced by the size of the cohort, and asked that the information about cohort size given to the panel was shared with the CAG.

Small numbers of patients may be involved, which may increase the risk of patient re-identification. Members requested details on how the applicants would handle the risk of re-identification and publication of small numbers.

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**

Support is required for the quantitative data collection. The research team will not have access to confidential patient information. It is also unlikely that the data controllers of the datasets used will be able to contact the parents/carers of the children involved. Contacting patients, or their parents/carers, may also cause distress, given the nature of AHT. The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

NHS Digital require access to confidential patient information in order to link confidential patient information from datasets held by other organisations to datasets they hold. The CAG agreed that the application 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 applicants provided the Privacy Notice (Evaluating ICON Privacy Notice), which will be displayed on the NIHR project website. The Privacy Notice contained email, telephone and postal contact details for the Chief Investigator.

The applicants explained that the dataset holders will be responsible for managing patients dissent to the individual datasets used. NHS Digital will apply the National Data Opt-Out.

Page 4 of the Privacy Notice contained the following passage under the heading “What are your rights?”, *“The data is held solely for research purposes. As an individual you have a right to be informed about the study, its use of the data, and how long we will hold the data for. When the project is completed you have a right for your data to be erased.”*

The CAG asked that this was revised to make it clear that patients can dissent to use of their information and don’t need to wait for the project to be completed before this can be requested.

Further details on the project specific opt-out needed to be provided. Telephone, postal and email contacts needed to be provided. Any leaflets to be used and patient notification and the text of any website or social media posts also needed to be provided.

The Notice should also provide further information about the project-specific opt-out, including postal, email and telephone contact details. In addition, other more accessible

notification materials, including leaflets, posters and/or social media posts, should be developed.

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 held a number of focus groups, with a total of 16 individuals involved in discussions. Two members of the initial PPI group have agreed to join the study team as co-investigators, providing advice on materials and methods. Several members of the PPI group have also agreed to be contacted during the study to explore any issues further. The PPI group was supportive of the use of confidential patient information without consent as described for the quantitative elements of the study. Those consulted noted that the use of identifiers should be avoided if possible, but determined that any risks arising from use of confidential patient information were offset by the importance of the condition studied, the large volume of data, and the routinely collected nature of the contents of the dataset.

The CAG agreed that the patient and public involvement and engagement carried out was of good quality, and raised no queries in this area.

Exit strategy

NHS Digital will delete the confidential patient information held by them for this study once the study completes. The pseudonymised dataset held at University Hospitals Bristol and Weston NHS Foundation Trust will be held for a maximum of ten years. The CAG raised no queries about the exit strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

Request for further information

1. Provide details on how the publication of small numbers and risk of re-identification would be handled.

2. The passage on page 4 of the Privacy Notice needs to be revised to make it clear that patients can dissent to use of their information and don't need to wait for the project to be completed before this can be requested.

3. Provide details about the revisions and additions to notification materials outlined on page 5 above

Specific conditions of support (provisional)

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. **Confirmed:**

   The NHS Digital **2020/21** DSPT reviews for **NHS Digital, NHS England, the National Child Mortality Database (University of Bristol), TARN (Northern Care Alliance NHS Foundation Trust) and PICANet (Universities of Leeds and Leicester)** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 20 June 2022).

8. Minutes of the meeting held on 07 April 2022.

The minutes of the meeting held on 07th April 2022 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
Dr Tony Calland, MBE, CAG Chair & Professor William Bernal, CAG Alternate Vice-Chair		*31 July 2022*
Signed – Confidentiality Advice Team		Date
Kathleen Cassidy, HRA confidentiality Advisor		*15 July 2022*