Understanding excess child and adolescent mortality in the United Kingdom compared with the EU15+ countries

Supplementary Material 1 (Chapters 1 and 2)

Data flow diagram and details of ethical approvals

Data Flow Diagram

Table S1 Data Flow Diagram Part 1

Data Provider		Data Transfer		Data Analysis		Outputs
Dataset A						
Provider Office for National Statistics (Child mortality statistics and Birth Cohort tables; mortality statistics from NOMIS) National Records Scotland (Vital Events Reference Tables) Northern Ireland Statistics and Research Agency (Registrar General Annual Reports) Description Annual number of deaths and rate per 100,000 by ICD coded cause, by sex, 5-year age group	→	Downloaded to personal computer from www.ons.gov.uk www.nomisweb.co.uk https://www.nrscotland.gov.uk https://www.nisra.gov.uk	→	Analysed on personal computer	→	Description of current mortality burden and trends over time in the UK, constituent countries, and 9 regions of England
Dataset B						
Provider WHO World Mortality Database Description National mortality estimates by cause of death in children and young people (CYP), age group and sex for UK and EU15+ countries 2001 – 2016. No identifiable data.	→	Downloaded to personal computer from http://www.who.int	→	Analysed on personal computer	→	International comparisons (UK and EU15+ countries) of national mortality rate by cause/sex/age group amongst children and young people 1-24 from 2001-2016

Table S2 Data Flow Diagram Part 2

Data Provider	Data Transfer	Data Analysis	Outputs
Dataset C			
Provider UK Data Service (UKDS) (Deposited by Office for National Statistics (ONS)) Description Death certification data for CYP living in England and Wales. Cause of death and socioeconomic variables. **Contains identifiable data.**	→ Data remains with UKDS– access to data provided via UKDS remote secure data lab	→ Analysed within UK Data Service remote secure data lab. Data fully anonymised prior to analysis (aggregated by age group / geographical region / cause of death / mortality rate meaned across 3-5 year periods) Extracted from secure lab after analysis. Extraction requires approval from UKDS that data anonymised	→ Comparison of mortality trends in England and Wales by geographic region and socioeconomic classification of parents 2001 - 2016

Table S3 Data Flow Diagram Part 3

Data Provider	Data Transfer	Data Analysis	Outputs

Dataset D

Hospital Episode Statistics data on secondary care use in England for all CYP 2007 – 2017.

Includes patient identifiable data

Office for National Statistics mortality data (details of death) for all CYP in England and Wales 2007 – 2017

Includes patient identifiable data

Provider
NHS Digital

Description
Pseudoannonymised Hospital Episode Statistics data on all secondary health service attendance linked to ONS mortality data amongst CYP 1-24 living in England from 2007 – 2017. **Linkage performed by NHS Digital.**

→

Transferred to UCL Data Safe Haven

→

Analysed within UCL Data Safe Haven

Data fully anonymised prior to analysis (aggregated by age group / geographical region / cause of death / mortality rate meaned across 3-5 year periods)

Extracted from UCL Data Safe Haven after analysis (fully anonymised)

→

Analysis of secondary health care usage amongst CYP prior to death in England for causes where the UK performs poorly, compared with age matched controls.

The lawful basis under which I am processing personal data (dataset C) is:
Article 6(1)(e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested the controller;
The lawful basis under which I am processing a special category of data (ie health data) is:
Article 9(2)(j) processing is necessary for archiving purposes in the public interest

Data Protection Compliance and General Data Protection Regulation (GDPR)

Most of the data used in this thesis is publicly available, however objective 3 and 4 requires processing personal data. The lawful basis under which I am processing personal data is:

Article 6(1)(e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested the controller;

The lawful basis under which I am processing a special category of data (ie health data) is:

Article 9(2)(j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

This project is necessary for scientific research purposes:
The research could not be undertaken without processing this data. In order to establish how patterns of healthcare use differ throughout England among CYP prior to death it is necessary to use hospital episode statistics data linked with mortality outcomes as described in the study protocol.

This project is in the public interest:
As described in the study protocol, there is a clear public interest in investigating why mortality rates amongst CYP in the UK are higher than in many other wealthy countries, so as to inform policies to improve outcomes. This includes investigating social and demographic factors which may influence higher mortality, but also exploring variability in health care use prior to death.

Consent:

Consent is not sought to use personal Hospital Episode Statistics data for research purposes. However, as the data requested did not include identifiable variables, I received confirmation from NHS digital that Confidential Advisory Group support under section 251 would not be required on Monday 13th August.

Transparency:

I have included details of the use of personal data in this study on my IRIS page here: https://iris.ucl.ac.uk/iris/browse/researchActivity/23320. This also gives details of the national opt out for CYP / parents to refuse to allow their health data to be made available to NHS digital for research.

Safeguards:

The research will not cause substantial damage or distress to data subjects. I will only request the minimum amount of personal data required to perform the analyses. Data will be aggregated by age group / causes of death / region of the country and so fully anonymised prior to analysis.

The project has been reviewed favourably by an NHS Research Ethics Committee

The data controller (UCL) has technical and organisational safeguards in place (IT security / data protection policies) to ensure the respect for the principle of data minimisation, and is compliant with the data security and protection toolkit. UCL privacy and data protection policies are available here https://www.ucl.ac.uk/legal-services/privacy.

Data subject's rights:

Details of how data subject's rights will be restricted in order to conduct the research are included in the transparency statement, and of how participants can opt out of sharing their personal data for non-clinical uses. We have also included contact details of the data-protection team for UCL so that participants are able to enquire about exercising their rights regarding their data.

NHS Research Ethics Committee / Confidential Advisory Group / Health Research Authority Documents

Health Research Authority

London - Brent Research Ethics Committee
80 London Road
Skipton House
London
SE1 6LH

Telephone: 02071048129

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

03 August 2018

Prof Russell Viner
30 Guilford Street
London
WC1N 1EH

Dear Prof Viner

Study title:	**Understanding excess child and adolescent mortality in the United Kingdom compared with EU15+ countries**
REC reference:	**18/LO/1267**
Protocol number:	**Version 1**
IRAS project ID:	**238618**

The Research Ethics Committee reviewed the above application at the meeting held on 23 July 2018. Thank you to Dr Joseph Ward for attending to discuss the application on your behalf.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Extract of the meeting minutes

Social or scientific value; scientific design and conduct of the study

The Committee questioned if Dr Ward had made a CAG submission.

Dr Ward clarified that the CAG team met last Friday and had sent some clarifications to be answered. The main concern is accessing data without consent and this would need REC approval as well.

The Committee sought clarification on whether the data collection from different regions and different time periods on each database, could come together or if it would make a difference to the findings.

Dr Ward clarified that he was restrained with how he could collect the data and would like to be able to look at the whole of the UK but this is complex merging different datasets. The first dataset would look at the UK, the second England and Wales, and the third England. There are limitations honing down on the UK.

The Committee questioned if Dr Ward would do all of the work himself or if he would be supported.

Dr Ward responded that his academic supervisors would help and he has statistical support from the Institute of Child Health. Dr Ward informed the Committee that he has experience working with big datasets and merging data.

The Committee sought clarification on whether there was a professional statistician on board working on the statistical plan.

Dr Ward confirmed this and explained that he would like to maintain the statistical plan but this may evolve throughout the study.

The Committee was satisfied with the responses detailed above.

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

The Committee commented that the study was a valuable piece of work and that it would be worthwhile spreading the results to other places and register it on other portals.

Dr Ward explained that this was a requirement for CAG, ensuring patients are aware that their data will be used. They have written a transparency statement on the UCLH website about how the data would be used and how patients can opt out. Dr Ward informed the Committee that the application to use death certificates means that the study can be viewed on approved researcher portal. With the National Children's Bureau, acceptability to use the data they have had discussions about the dissemination of results.

The Committee was satisfied with the response detailed above.

Please contact the REC Manager if you feel that the above summary is not an accurate reflection of the discussion at the meeting.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UCL Insurance Certificate]	1	24 July 2017
IRAS Application Form [IRAS_Form_27062018]		27 June 2018
Letter from funder [MRC Offer Letter]	1	24 July 2017
Other [Summary CV of second supervisor]	1	04 July 2018
Research protocol or project proposal [Project Protocol]	1	28 January 2018
Summary CV for Chief Investigator (CI) [Russell Viner CV]		
Summary CV for student [Joseph Ward CV]	1	14 June 2018
Summary CV for supervisor (student research) [Russell Viner CV]	1	14 June 2018

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

18/LO/1267	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Manish Saxena
Chair

E-mail: nrescommittee.london-brent@nhs.net

Enclosures:	*List of names and professions of members who were present at the meeting and those who submitted written comments*
	"After ethical review – guidance for researchers"
Copy to:	*Ms Emma Pendleton, Division of Research and Innovation, UCL GOS Institue of Child Health*
	Ms Emma Pendleton, Division of Research and Innovation, UCL GOS Institue of Child Health
	Confidentiality Advise Team

London - Brent Research Ethics Committee

Attendance at Committee meeting on 23 July 2018

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Suresh Akula	Retired Civil Servant	Yes	
Dr Daniel Bradford	Pharmacologist	Yes	
Mr James Cann	Medical Writing Senior Manager	Yes	
Ms Iona Crawford	Associate Mental Health Worker	Yes	
Dr Graham Davison	Pharmaceutical Consultant	Yes	
Dr Anke Furck	Consultant in Paediatric Intensive Care	Yes	
Mrs Diana Harvey	Lawyer	Yes	
Mr Maurice Hoffman	Retired Teacher	Yes	
Dr Dusko Ilic	Reader in Stem Cell Science	No	
Professor Ramesh Kapadia	Retired Education Consultant	Yes	
Dr Prashanth Nandhabalan	Specialist Registrar in Intensive Care and Anaesthesia	No	
Dr Manish Saxena	Clinical Lecturer	Yes	(Chair)
Ms Sibonginkosi Sibanda	Advanced Nurse Practitioner	No	
Dr Zdenek Slavik	Consultant Paediatric Cardiologist/Intensivist	Yes	
Dr Krishna Soondrum	Consultant Paediatric Gastroenterologist	Yes	
Mrs Lynda Wirth	Medical Publisher	Yes	
Miss Zainab Yate	Bioethics Researcher	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Ian Cook	HRA Observer
Miss Nicole Curtis	REC Manager

Written comments received from:

Name	*Position*
Professor Ramesh Kapadia	Retired Education Consultant

Health Research Authority

Skipton House
80 London Road
London
SE1 6LH

Telephone: 020 7972 2557
Email: hra.cag@nhs.net

02 August 2018

Professor Russell Viner
UCL GOS Institute of Child Health
30 Guilford Street
London
WC1N 1EH

Dear Professor Viner

Application title:	**Understanding excess child and adolescent mortality in the United Kingdom compared with EU15+ countries**
CAG reference:	**18/CAG/0117**
IRAS project ID:	**238618**
REC reference:	**18/LO/1267**

Thank you for your research application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether an application should be approved, and if so, any relevant conditions. This application was considered at the precedent set CAG meeting held on 13 July 2018. The application was considered via the Precedent Set process under criteria four – time limited access to undertake record linkage/validation and anonymise the data.

Health Research Authority Decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application is provisionally approved, subject to satisfactory responses to the request for further information and compliance with the standard and specific conditions of approval.

Please note support to process confidential patient information without consent is not yet in effect.

Context

Purpose of Application

This application from University College London Great Ormond Street Institute of Child Health set out the purpose of medical research which aims to investigate why the infant mortality rate within the United Kingdom is higher than in many other developed countries.

The project involves three phases:

- A comparison of the UK childhood mortality rates with other similar nations using information available from the World Health Organisation. This information is publicly available and does not form part of the application to the CAG.
- Investigation of mortality rates for specific non-communicable diseases, for example asthma, diabetes and cancer in England and Wales from 2001-2016. The applicant will access death certification information for children and young people in England and Wales within a dataset retained by the UK Data Service, provided by the Office of National Statistics. This will also allow analysis of regional trends by geographical area and socioeconomic status. This information has been compiled from death certificates and does not require support under the Regulations.
- Analysis of secondary health care usage amongst children and young people prior to death in England only. This analysis will be undertaken on a linked HES and ONS mortality information dataset which will be created by NHS Digital for the purposes of the project. The CAG is being asked to consider providing support to the data processing which will be undertaken NHS Digital in order to create the analysis dataset.

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

Confidential Patient Information Requested

Cohort

- All children and young people aged 1 to 24 who have accessed secondary health services (Accident and Emergency, outpatient, inpatients) in England between 2001 and latest available (identified through Hospital Episode Statistics data).
- A sub-cohort of deceased patients will be identified within this overarching cohort to be used as a comparator.

The following items of confidential patient information are required for the purposes as described below:

- NHS Number – linkage,
- Date of birth – linkage and used to calculate age at death for analysis,
- Date and cause of death – linkage and used to calculate age at death for analysis,
- Postcode – linkage and used to calculate age at death for analysis,
- Gender – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public Interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. It was agreed that there was a clear public interest in gaining a better understanding of why the infant mortality rates are higher in the UK than other developed countries.

Scope of Support

The Group considered the various phases within the overarching application activity and it was agreed that the first two elements were out of the CAG's remit and did not require a recommendation of support under the Regulations.

Members considered the data linkage which was detailed for the third part of the project and it was recognised that NHS Digital would be providing information from the already linked HES-ONS dataset which they retain for the purposes of the project. The Group was unclear why support under the Regulations was required for this activity, as it was recognised that NHS Digital provided this linkage service as standard. An inconsistency in the information provided on the data flow diagram for this element of the application was also identified. The explanation provided stated that pseudonymised data would be provided by NHS Digital, but then also stated that the extract contained identifiable information. The CAG agreed that further information was required in relation to this element of the study in order to understand why support was required. Written confirmation provided by NHS Digital, as the controller providing this data, is required to explain why the proposed activity requires a recommendation of support. Clarification was also required around what data would be released from NHS Digital for both patients and controls, in order to establish whether this data flow would require a recommendation of support under the Regulations.

Practicable Alternatives

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

- Feasibility of consent

It was recognised that consent was not feasible as the patient cohort for inclusion was deceased.

- Use of anonymised/pseudonymised data

The Group acknowledged that a query had already been raised in relation to the processing and disclosure of confidential patient information for the purposes of the application to enable an assessment to be made in this area.

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 an unconsented activity should go ahead.

It was recognised that the project was to the National Children's Bureau (NCB) Young Research Advisors Group. The acceptability of the research methods and dissemination plans were discussed at a focus group which involved 25 children and young people aged between seven and 24 years. It was confirmed that there were further plans to re-engage with the group to seek guidance around the dissemination of findings at a later stage in the project. No issues were raised in this area.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 2018.

It was recognised that a notification would be displayed on the UCL website in relation to the project. Due to the lack of clarity around the data which would be released from NHS Digital, Members commented that there was potential that the content of the documentation may need to be revised to clearly explain the dataset which would be accessed, to enable those patients who were included as controls to identify themselves as part of the project. No specific action could be requested as this stage pending confirmation of the content of the data set.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. Evidence would need to be provided that an ethical opinion was in place for the study before any recommendation of support could come into effect.

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for Further Information

1. Provide written correspondence from NHS Digital to clarify which element of the overall application activity they have determined requires a recommendation of support under the Regulations in order to legitimise data processing.
2. Provide a clear overview of what data will be released by NHS Digital from the linked HES-ONS dataset, specifying what items of confidential patient information would be included as necessary. Confirmation is also required around whether the same level of data would be required for patients within the control sample.

Once received, the information will be reviewed by a sub-committee of members, in the first instance and a recommendation and decision issued as soon as possible. At this

stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the HRA will confirm approval.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – UCL School of Life and Medical Sciences – V14.1, 2017/18 – reviewed satisfactory and NHS Digital – undertaking data processing**).

Reviewed Documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from (signed/authorised) [CAG Form]		27 June 2018
Data Protection Registration [16PP37 Data Protection Form]		
Data Protection Registration [16PP37 Data Protection Registration]		27 August 2017
Other [Initial Application Queries]		
Other [18CAG0117 CAT Advice Form Complete]		11 July 2018
Other [Communications plan]		
Other [IRIS Text Transparency Statement]		
Research protocol or project proposal [Data Flow Diagram]		
Research protocol or project proposal [Protocol Joseph Ward IRAS 238618]	1	28 January 2018
Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [9. HRA letter of recommendation - Excess child mortality study]		30 May 2018

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item or submitted written comments are listed below.

Yours sincerely

Miss Kathryn Murray
Senior Confidentiality Advisor

On behalf of the Health Research Authority

Email: HRA.CAG@nhs.net

Enclosures: *List of members who considered application*
Standard conditions of approval

Copy to: NRESCommittee.London-Brent@nhs.net

Confidentiality Advisory Group Sub-Committee Meeting 13 July 2018

Group Members:

Name	*Present*	*Notes*
Ms Sophie Brannan	No	
Dr Patrick Coyle	Yes	Vice Chair
Dr Lorna Fraser	Yes	
Mr Anthony Kane	Yes	
Dr Harvey Marcovitch	No	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Standard conditions of approval

The approval provided by the Health Research Authority is subject to the following standard conditions.

The applicant will ensure that:

1. The specified patient identifiable information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant.

4. All staff with access to patient identifiable information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to patient identifiable information have received appropriate ongoing training to ensure they are aware of their responsibilities.

6. Activities are consistent with the Data Protection Act 2018.

7. Audit of data processing by a designated agent is facilitated and supported.

8. The wishes of patients who have withheld or withdrawn their consent are respected.

9. The Confidentiality Advice Team is notified of any significant changes (purpose, data flows, data items, security arrangements) prior to the change occurring.

10. An annual report is provided no later than 12 months from the date of your final confirmation letter.

11. Any breaches of confidentiality / security around this particular flow of data should be reported to CAG within 10 working days, along with remedial actions taken / to be taken.

Ref: NIC-141410-W6H4Y - DARS - Form Submitted

NHS Digital Enquiries (NHS DIGITAL) <enquiries@nhsdigital.nhs.uk>

Mon 13/08/2018 15:35

Inbox

To:Ward, Joseph <joseph.ward@ucl.ac.uk>;

Ref: NIC-141410-W6H4Y

Dear Joe,

Thank you for your email.

Please see the response from the Data Applications Team below:

-

From a NHS Digital DARS perspective, with regards to the requirement for CAG Section 251 approval , if you are not sending a cohort to NHS Digital and only requesting HES data that is pseudonymised along with Civil Registration Deaths data then this will not require section 251 approval evidence. If you will be providing a cohort and/or requesting identifiable data then Section 251 approval evidence will be required.

If you feel you do require a Section 251 please let us know and we can provide you with a response advising of the requirement.

-

Kind Regards,

Danielle Gilmore

Contact Centre Team
NHS Digital
www.digital.nhs.uk

0300 303 5678
enquiries@nhsdigital.nhs.uk

1 Trevelyan Square | Boar Lane | Leeds | LS1 6AE

You can find out more about our service, including our response times and customer charter on the NHS Digital website: https://digital.nhs.uk/about-nhs-digital/contact-us/nhs-digital-customer-service-centre

---------- Original Message ----------
From: joseph.ward@ucl.ac.uk;
Received: 2018-08-08T15:29:40Z
To: enquiries@nhsdigital.nhs.uk; enquiries@nhsdigital.nhs.uk; enquiries@nhsdigital.nhs.uk; enquiries@nhsdigital.nhs.uk;

enquiries@nhsdigital.nhs.uk; enquiries@nhsdigital.nhs.uk; enquiries@nhsdigital.nhs.uk;
Subject: Query regarding need for CAG Support

Dear NHS Digital

Reference: DARS-NIC-141410-W6H4Y-v0.0

Project title: Understanding excess child and adolescent mortality in the UK

I am nearly ready to submit my application for individual level HES data, but would like to discuss this with a member of your team.

Specifically, I would like to enquire about the need for confidential advisory group (CAG) support. I have applied to CAG and received a letter detailing provisional support, on the condition that I provide written confirmation from NHS digital that CAG support is needed.

How would I be able to determine if I need CAG support, and if I do please can I request written confirmation of this?

Best Wishes

Joe Ward

RE: IRAS 238618 - HRA Assessment Query

GREENFIELD, Laura (HEALTH RESEARCH AUTHORITY) <lauragreenfield@nhs.net>

Fri 20/07/2018 10:01

Inbox

To:Ward, Joseph <joseph.ward@ucl.ac.uk>; Viner, Russell <r.viner@ucl.ac.uk>; research.governance@gosh.nhs.uk <research.governance@gosh.nhs.uk>;

Cc:BRENT, NRESCommittee.London- (HEALTH RESEARCH AUTHORITY) <nrescommittee.london-brent@nhs.net>; CAG, HRA (HEALTH RESEARCH AUTHORITY) <hra.cag@nhs.net>;

Dear Joseph,

As there is no NHS Primary or Secondary care involvement for this study you will not require HRA Approval. Your study will still proceed to REC and CAG approval accordingly.

Kind regards,

Laura

Laura Greenfield
Assessor
Health Research Authority
The Old Chapel | Royal Standard Place | Nottingham | NG1 6FS
T. 020 7104 8096
E. lauragreenfield@nhs.net
W. www.hra.nhs.uk

Sign up to receive our newsletter HRA Latest.

From: Ward, Joseph [mailto:joseph.ward@ucl.ac.uk]
Sent: 20 July 2018 09:58
To: GREENFIELD, Laura (HEALTH RESEARCH AUTHORITY); Viner, Russell; research.governance@gosh.nhs.uk
Subject: Re: IRAS 238618 - HRA Assessment Query

Dear Laura

I can confirm that this project will only be accessing NHS data from central sources (NHS digital and the Office for National Statistics) and there will be no involvement from Primary or Secondary care organisations.

Best Wishes

Joe

From: GREENFIELD, Laura (HEALTH RESEARCH AUTHORITY) <lauragreenfield@nhs.net>
Sent: 20 July 2018 08:43:47
To: Viner, Russell; Ward, Joseph; research.governance@gosh.nhs.uk
Subject: IRAS 238618 - HRA Assessment Query

Dear Prof. Viner,

I have recently reviewed your study IRAS 238618 Understanding excess child and adolescent mortality in the UK. Can you please confirm that this study is only accessing NHS data from central sources only and there is no involvement of NHS primary or secondary care organisations?

Kind regards,

Laura

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