Health Research Authority

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22 October 2020

Dr Richard Feltbower
Leeds Institute for Data Analytics
School of Medicine
University of Leeds
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Dear Dr Feltblower,

Application title:	**Yorkshire Specialist Register of Cancer in Children and Young People**
CAG reference:	**20/CAG/0133**
IRAS project ID:	**287792**
REC reference:	**00/3/001**

Thank you for submitting a **research** application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') to process confidential patient information without consent.

Supported applications allow the controller(s) of the relevant data sources, if they wish, to provide specified information to the applicant for the purposes of the relevant activity without being in breach of the common law duty of confidence. Support provides a lawful basis to allow the information to be processed by the relevant parties for the specified purposes without incurring a breach of the common law duty of confidence only. Applicants must ensure the activity remains fully compliant with all other relevant legislation.

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 application activity should be supported, and if so, any relevant conditions. This application was considered at the CAG meeting held on 15 October 2020. It should be noted that this an updated submission of a previously supported CAG application, CAG 1-07(b)/2014, submitted following a request from CAG when supporting an amendment on 18 October 2019.

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 to allow the disclosure of confidential patient information between University of Leeds and Local NHS Trusts, EMIS, TPP, NHS Digital, Public Health England, Department of Education and Department of Work and Pensions is conditionally supported, subject to compliance with the standard and specific conditions of support.

   Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

   Context

   Purpose of application

   This application, from the University of Leeds, sets out the purpose of establishing a database for medical research purpose, which aims to undertake research on the area of cancer.

   Cancer is a rare disease in children and young people and one that places a considerable burden not only upon the patients themselves but also on their families and the health care system. Little is known about the causes in this young age group. The Yorkshire Specialist Register of Cancer in Children and Young People is an established population-based register of tumours diagnosed in the childhood, adolescent and young adult age ranges. The Register currently contains information on 10,500 young people diagnosed with cancer while living within the former Yorkshire Regional Health Authority.

   The primary aim of the Register is to investigate the causes of cancer through the application of epidemiological analyses. This includes monitoring time trends and investigating geographical patterns of disease across the region. Secondly, our aim is to investigate the delivery of care to young people with cancer in Yorkshire to ensure the best treatment is available and to minimise long-term health and social effects; for example by looking at pathways of care, factors that influence survival and minimise long-term complications.

   Support is requested to enable sharing of confidential patient information between University of Leeds and Local NHS Trusts, EMIS, TPP, NHS Digital, Public Health England, Department of Education and Department of Work and Pensions in order to establish and maintain a research database. The database contains around 10,500 young people and linkages continue to be sought for these people. Linkages occur at monthly/quarterly intervals and each includes transfer of identifiers from the register to the organisation, with pseudonymised data returned (identified by study ID). For PHE, names are also returned to trace individuals' records in medical record departments in order to fill in any missing clinical information. For Trusts, the register receives a regular feed from the electronic health record systems.

   In addition, prospective patients continue to be included in the registry. New childhood cases are notified by the 2 Principal Treatment Centres in Yorkshire: Leeds Teaching Hospitals NHS Trust and Sheffield Children's Hospital through nhs.net secure email and through NCRAS data from PHE for Teenage and Young Adult cases. Once these new cases are added, linkages with the above databases will continue.

   The database is used for research purposes to which research teams can apply access to. Following approval by the advisory committee the researchers will be provided with an anonymised data extract. Note the protocol states that where the applicant requests identifiers (e.g. to contact the patient) this will require a separate application for support.

Confidential patient information requested

Cohort	All individuals between 0-29 diagnosed with a malignant (or benign central nervous system) tumour whilst resident in the area contiguous with the former Yorkshire and the Humber SHA region. Retrospectively data has been included in the registry since 1974. The data will also include prospective patients
Data sources	1. Local NHS Trusts 2. EMIS 3. TPP 4. NHS Digital (HES inpatient, outpatient, A&E and Mental Health datasets) 5. Public Health England (National Cancer Registration Service, Radiotherapy Dataset, Chemotherapy treatment, Systemic Anti-Cancer therapy dataset). 6. Department of Education 7. Department of Work and Pensions
Identifiers required for linkage purposes	1. NHS number 2. Date of Birth 3. Date of Death 4. Postcode
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode 4. Gender 5. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

The CAG noted that this was a revised application of a research database which is currently operating under Regulation 5 support. The members noted the extremely important outputs that the database has already achieved in the field of children and young people with cancer, and that the activity is justified as being in the public interest.

This is a research application and members wished to reinforce that the data is only used for medical research purposes. Any use for non-research purposes, in the management of health and social care, will require a separate application.

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 stated that consent is not feasible given the large retrospective cohort involved, that contacting patients may cause unnecessary stress at a difficult time, and the need for a complete dataset to produce accurate outputs.

The CAG considered these points and agreed that the consent is not feasible.

- Use of anonymised/pseudonymised data

Members agreed that it is not possible to undertake these activities without the use of confidential patient information, and that the applicants are minimising the use of confidential patient information as far as possible.

'Patient Notification' and mechanism for managing dissent

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

Members noted the strides that the applicant has undertaken to improve the patient notification materials since a previous amendment was supported in October 2019.This was particularly relevant for the information sheets for children and young people.

The group did notice that the poster provided did not include information on how patients can opt out of their data being used and requested this is updated. Further, the opt out process document did not state that opting out will not affect the care provided and requested that this is also updated. Updates made on these points should be provided at the next annual review.

Lastly, members felt that the website remained hard to navigate (a comment noted on the supported amendment letter of 18 October 2020), and requested that the applicant reviews this and adds a menu item to make it easier for patients to navigate to the information about data held, security arrangements and the process for opting out; and reports back at the next annual review. Further, the PDF documents in that area should have clear titles that point to the relevant content for people considering whether to dissent, rather than just filenames.

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 group understood the further work that the applicant has undertaken in patient and public involvement, with plans to continue this with the development of a Young Persons Advisory Group and commended this work. Members requested, at the time of the next annual review, to be provided with details on the make up of the Young Persons Advisory Group.

It was also noted that the Advisory group that considers requests for data does not currently have any lay representation. Members requested that the applicants look to include lay members in this group, reporting back at the next annual review. The group also suggested that there is a link between the Young Persons Advisory Group and the Advisory group that considers requests for data.

System Architecture

The group understood that there are plans to update the system architecture which holds the confidential patient information. Members requested further details of this change to be provided at the next annual review.

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

1. At the next annual review provide confirmation that the study website has been revised to make it easier for patients to access full information.

2. At the next annual review, provide an updated poster which details the mechanism for opting out of use of data.

3. At the next annual review, provide details on the make up of the Young Persons Advisory Group.

4. At the next annual review, provide confirmation that at least one lay person has been appointed to the Advisory Group that reviews requests for data. It is also suggested that there are formal links between the Young Persons Advisory Group and the Advisory Group that reviews requests for data.

5. At the next annual review, provide an update on the change of system architecture at the University of Leeds.

6. At the next annual review confirm that the opt out information provided to patients has been updated to clarify that opting out will not affect the care of the patient.

7. Support for this application has been provided for medical research purposes only. Where the data is to be used for non-research purposes in the management of health and social care a separate application for support should be submitted.

8. Support is provided on the understanding that data provided to researchers is effectively anonymised. Where a researcher requests identifiable data, a separate, project specific application should be submitted for support.

9. Favourable opinion from REC **Received 15 May 2000 (updated through amendments since)**

10. 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. **The NHS Digital DSPT submission for University of Leeds (18/19), NHS Digital (19/20), EMIS (19/20, and TPP (19/20) were confirmed as 'Standards Met' by NHS Digital (by check of DSPT tracker on 18 October 2020).**

    The NHS digital review for Department for Education (19/20) and Department for Work and Pensions (19/20) confirmed that equivalent standards have been met (by check of DSPT tracker on 18 October 2020).

    The NHS Digital DSPT submission for Public Health England (18/19) was confirmed as 'Standards Not Fully Met (Plan Agreed)' on the NHS Digital DSPT Tracker (checked 18 October 2020). Please note the updated specific condition of support below.

    Public Health England should achieve the security assurance action plan as agreed with NHS Digital. All staff involved in processing information under this application reference should be aware of the precise scope of support and its boundaries and have successfully completed local security awareness training before processing any information under support.

As the above conditions have been accepted or met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Application maintenance

Annual review

Please note that this legal support is subject to submission of an annual review report, for the duration of support, to show that the minimal amount of patient information is being processed and support is still necessary, how you have met the conditions or report plans, any public benefits that have arisen and action towards meeting them. It is also your responsibility to submit this report every 12 months for the entire duration that confidential patient information is being processed without consent.

The next annual review should be provided no later than **22 October 2021** and preferably 4 weeks before this date. Reminders are not issued so please ensure this is provided annually to avoid jeopardising the status of the support. Submission of an annual review in line with this schedule remains necessary even where there has been a delay to the commencement of the supported activity, or a halt in data processing. Please ensure you review the HRA website to ensure you are completing the most up to date 'section 251' annual review form as these may change.

For an annual review to be valid, there must also be evidence that the relevant DSPT submission(s) for organisations processing confidential patient information without consent are in place and have been reviewed by NHS Digital. Please plan to contact NHS Digital in advance of the CAG annual review submission date to check they have reviewed the relevant DSPTs and have confirmed these are satisfactory.

Register of Approved Applications

All supported applications to process confidential patient information without consent are listed in the published 'Register of Approved Applications'. It is a statutory requirement for the Register to be published and it is available on the CAG section of the Health Research Authority website. It contains applicant contact details, a summary of the research and other pertinent points.

This Register is used by controllers to check whether support is in place.

Changes to the application

The application and relevant documents set out the scope of the support which is in place for the application activity and any relevant restrictions around this.

Any amendments which are made to the scope of this support, including but not limited to, purpose, data flows, data sources, items of confidential patient information and processors, require submission of a formal amendment to the application. Changes to processors will require evidence of satisfactory DSPT submission. The amendment form can be found in the Confidentiality Advisory Group pages on the Health Research Authority website.

Support for any submitted amendment would not come into effect until a positive outcome letter has been issued.

Changes to the controller

Amendments which involve a change to the named controller for the application activity require the submission of a new and signed CAG application form and supporting documentation to support the application amendment. This is necessary to ensure that the application held on file appropriately reflects the organisation taking responsibility for the manner and purpose of data processing within the application, and that the legal support in place is related to the correct legal entity.

Applicants are advised to make contact with the Confidentiality Advice Team to discuss a change in controllership for an existing application in sufficient time ahead of the transfer of project responsibility to discuss the submission process timings.

Further information and relevant forms to amend the support is available on the HRA website.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from (signed/authorised) [CAG_17092020_finalsubmitted]		09 September 2020
Other [Data Collection Data Flows_sep20]		September 2020
Other [Data Flow Diagram - Primary Care_V1]	1.0	
Other [SEED Information Governance policy]	5.0	February 2019
Other [CG equivalent support]		09 September 2020

Patient Information Materials [Data Flow Protocol - Lay summary_220618]		
Patient Information Materials [Data_Collection_Form]	1.01	
Patient Information Materials [YSRCCYP Database opt out policy 2020]	1.5	August 2020
Patient Information Materials [IL Leaflet_under16sv2_final]	2	March 2020
Patient Information Materials [IL Patients_16+_March2020v15l]	15	March 2020
Patient Information Materials [IL ParentsGuardians_March2020v15]	15	March 2020
Patient Information Materials [YSRCCYP_poster_ver6]	6	
Patient Information Materials [PrivacyandFairProcessingStatement]	1.5	September 2020
Research protocol or project proposal [Protocol_Apr2018_v10_clean]	10	April 2018

Membership of the Committee

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

Lorna Fraser declared an interest for this item and left the meeting when it was considered.

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/

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

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

Yours sincerely

Paul Mills
Confidentiality Advice Service Manager

On behalf of the Health Research Authority

Email: cag@hra.nhs.uk

Included: List of members who considered application
Standard conditions of support

Copy to: york.rec@hra.nhs.uk

Confidentiality Advisory Group meeting attendance
15 October 2020

Members present:

Name	
Dr Patrick Coyle	CAG vice-chair
Dr Lorna Fraser	CAG member
Dr Rachel Knowles	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Harvey Marcovitch	CAG member
Mr Andrew Melville	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Mr Marc Taylor	CAG member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Health Research Authority

Standard conditions of support

Support to process the specified confidential patient information without consent, given by the Health Research Authority, is subject to compliance with the following standard conditions of support.

The applicant and those processing the information under the terms of the support will ensure that:

1. The specified confidential patient 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, in addition to other national guidance.

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

5. All staff with access to confidential patient information have received appropriate ongoing training to ensure they are aware of their responsibilities and are acting in compliance with the application detail.

6. Activities must be compliant with the General Data Protection Regulation and 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. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be approved via formal amendment prior to changes coming into effect.

10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.

11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken/to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.