Health Research Authority

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17 December 2020

Professor Eve Roman
Professor/ Director of the Epidemiology & Cancer Statistics Group
University of York
Department of Health Sciences
University of York
YO10 5DD

Dear Professor Roman

Application title:	**Yorkshire & Humberside Haematology Network Register**
CAG reference:	**20/CAG/0149**
IRAS project ID:	**289074**
REC reference:	**04/Q1205/69**

Thank you for your research application, submitted for support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information without consent. Supported 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 supported, and if so, any relevant conditions. This application was considered at the CAG meeting held on 03 December 2020.

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 research nurses to access confidential patient information, held at the HMDS at Leeds Teaching Hospitals NHS Trust, in order to identify suitable patients and seek consent for inclusion in the Register and to allow patients deemed suitable, but who were too unwell to be approached or died before consent could be sought, to be included in the Register is conditionally supported, subject to compliance with the standard and specific conditions of support outlined below.

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 York set out a refreshed application for the Yorkshire & Humberside Haematology Network Register (YHHN Register). This Register was created to provide a comprehensive population-based patient cohort ("registry") of patients newly diagnosed with haematological malignancies in the regions covered by the West Yorkshire & Harrogate and Humber, Coast & Vale Cancer Alliances.

Haematological malignancies are comprised of a heterogenous group of cancers, with differing treatments and prognoses. Haematological cancers comprise a comparatively neglected cancer group, largely because of the complexities associated with their diagnoses and treatment. The YHHN Register was set up to monitor patient care by collating clinical and demographic real-world data, combined with accurate and complete follow-up information. The Register covers a population of around 4 million. In addition to the provision of real-world descriptive data for commissioning purposes and national guidelines, the YHHN Register also provides the infrastructure to facilitate studies in other research areas, which includes; examining the potential causes of haematological cancers and investigating factors associated with a delay in diagnosis, gaining a greater understanding of the biology of these tumours to potentially improve disease management and outcome, and investigating health inequalities, summarizing health resource utilization and costing the treatment pathways, and examining end-of-life of care and place of death.

The patient population is comprised of adults and children who were newly diagnosed with a haematological malignancy on or after 1 September 2004, who are resident in West Yorkshire & Harrogate and the Humber, and Coast & Vale Cancer Alliances. Informed consent is sought from patients whenever possible, however, due to the nature of haematological cancers, it may not always be possible to obtain consent. This may be due to aggressive disease and/or co-morbidities, meaning patients are too unwell to be consented, or have died before consent could be sought. Patients may also have died before a formal diagnosis of haematological malignancy was diagnosed. In 2007, the applicants sought exemption under Section 60 of the Health and Social Care Act 2001 (PIAG 1-05(h)/2007). A refreshed application has now been submitted to update the application and to add Hull University Teaching Hospitals NHS Trust as a joint data controller, alongside the University of York.

As part of the routine diagnostic process, samples from patients across the Network are sent to the Haematological Malignancy Diagnostic Service (HMDS) based at Leeds Teaching Hospitals NHS Trust. Patients' name, date birth and NHS number are sent with the sample and entered onto MHDS's web-based sample tracking and reporting system, HMDS Information Laboratory Integrated System (HILIS). The applicants have support under s251 to allow research nurses, employed by the University of York, to access confidential patient information within HILIS to identify suitable patients and seek their consent for inclusion in the study. Support is also requested to allow patients who were too unwell to be approached for consent or died before they could be approached. The research nurses will liaise with the patient's clinical team to determine whether they are too unwell to be approached for consent. Where patients are too unwell, the research team will check with the clinical care team at a later date to ascertain whether patients are well enough to be consented. Approximately 6 months after the diagnosis, the applicants will begin the data collection process. A cancer-specific data collection form is generated from the patient's HILIS record at LTHT. This form is sent to the patient's treating hospital for prognostic, treatment and outcome data to be abstracted from the

medical records. Data abstraction is then undertaken for consented and non-consented patients by University of York research nurses. For all patients, a pseudonymised dataset is download from HILIS containing demographic, diagnostic, prognostics, treatment and outcome data. No identifiable data will be included, and this file is securely exported to the University of York where data are analysed. Confidential patient information will be disclosed from the University of York to NHS Digital to HES, Death notification and cancer registration datasets held by NHS Digital. Data received from NHS Digital does not contain any personal identifiers, just the study identifier; and these data are stored in their own separate database.

A recommendation for class 1, 2, 3, 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	Adults and children (from age 0 upwards) newly diagnosed with a haematological malignancy whilst resident in the regions covered by the West Yorkshire & Harrogate and Humber, Coast & Vale Cancer Alliances. Since the inception of the study in 2004 to date, approximately 36,000 patients have been ascertained. 2,500 are added each year. The applicants estimate that 45,000 patients will have been recruited by the current planned end date of September 2024 and that approximately 27,500 of this number will not have given consent.
Data sources	1. Electronic diagnostic and pathology records held on the Haematological Malignancy Diagnostic Service's (HMDS) Integrated Laboratory Information System (HILIS) 2. HES, Death notification and cancer registration data held by NHS Digital 3. Hospital medical records at participating trusts: a. Airedale NHS Foundation Trust b. Bradford Teaching Hospitals NHS Foundation Trust c. Calderdale and Huddersfield NHS Foundation Trust d. Harrogate and District NHS Foundation Trust e. Hull University Teaching Hospitals NHS Trust f. Leeds Teaching Hospitals NHS Trust g. Mid Yorkshire Hospitals NHS Trust h. Northern Lincolnshire and Goole NHS Foundation Trust i. York Teaching Hospital NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID number 4. GP Registration 5. Date of birth

	6. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – unit level 4. Gender 5. Occupation 6. 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.

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 will consent patients where possible but are seeking support to include patients who could not be consented, either because they were too unwell to be consented or died before consent could be sought.

The CAG noted that most participants would not have given consent. This included deceased patients and those too unwell to be approached, but also a large number of patients who would have been approached for consent but would not have responded. Members noted that guidance from the Information Commissioner's Office was that non-response was to be considered as dissent and not assent. Therefore, if patients were approached for consent but did not respond to the approach, then their confidential patient information could not be processed under s251 support. The CAG asked that further details were given on the consent process and how non-responders had been dealt with so far.

Some patients may be too unwell to be approached or lack capacity to consent. The CAG noted that s251 support could only be used as a last resort, if no other legal basis for processing confidential patient information was available. The applicants needed to determine whether a legal basis under the Mental Capacity Act could be used for adults lacking capacity.

The CAG asked the applicants to explain how patients who did not respond to requests for consent via post had been dealt with until now.

- Use of anonymised/pseudonymised data

Confidential patient information is required to link patients across various datasets. This cannot be undertaken in any other way.

'Patient Notification' and mechanism for managing dissent

The patient notification and dissent process described is focused on patients who will be consented.

The applicants had provided an "Appendix" document, which included information materials to be used by hospitals when informing patients about the Register. These materials would be used in haematology outpatient clinics and at events held by individual hospitals to publicise ongoing research. These materials included contact details for YHHN.

The Yorkshire and Humberside Haematology Network project website also contains the Privacy Notice for the project, which explains how personal information will be collected and processed, and contact details for patients to request that use of their data is restricted.

The information given in the application relates to patients approached for consent. The applicants have provided contact details for the YHHN team on the patient information materials, but the ability to opt-out and how to do so is not clearly described. The CAG noted that the patient notification was dated. Members asked that the applicants work with their patient and public involvement groups to bring the notification materials up to date. The role the University of York plays in the study needs to be fully explained.

Patient and Public Involvement and Engagement

The applicants advised that, since 2009, YHHN has had an established Patient Partnership, which works in collaboration with researchers and members of the Clinical Network. The Patient Partnership, which spans the two former Cancer Networks of Yorkshire & Humber and Yorkshire Coast, is a formally recognized entity, and its activities are overseen by a Steering Group which meets at regular intervals to discuss patient, carer and public involvement across the project as a whole. The partnership currently has over 900 members (patients and carers); all of whom have agreed to participate in research either by sharing their experiences and/or by commenting on YHHN research activities. Members of the Partnership routinely input into YHHN funding applications, acting as co-applicants and feeding into work streams at study management meetings. Members also continue to take part in focus groups, complete questionnaires, and help to review YHHN literature and update the website. This committee is aware that information may be used without consent and take this into consideration when discussing YHHN and its nested studies.

Use of identifiable data without patient consent has also been discussed at length with members of the Network Audit Committee, which includes patient and relative representation. Issues such as linkage to data from routine sources from NHS Digital have also been raised at these meetings.

The applicants advised that a steering committee had been set up to oversee the projects that are embedded in the YHHN Register. At least one service user was included in this committee. The setting up of studies, the findings of the research and how they will be disseminated are discussed at meetings of the steering committee.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending 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. Further clarification on the consent process and the scope of the s251 sought is required:

    a. Provide further clarification on the consent process and how non-responders have been dealt with so far.

    b. Clarify if a legal basis under the Mental Capacity Act could be used for adults lacking capacity.

2. The patient notification material needs to be revised and updated, in collaboration with the patient and public involvement group, and the role of the University of York fully explained.

3. Favourable opinion from a Research Ethics Committee. **Confirmed 03 September 2004.**

4. 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.

- University of York – Department of Health Sciences – DSPT pending for 2019/20
- Hull University Teaching Hospitals NHS Trust – DSPT pending for 2019/20
- Leeds Teaching Hospitals NHS Trust - DSPT pending for 2019/20
- **Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.**

As the above conditions have been accepted, 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.

Annual Review

Please note that your support is subject to submission of an annual review report to show how you have met the conditions or report plans, and action towards meeting them. It is also your responsibility to submit this report on the anniversary of your final support and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements. An annual review should be provided no later than **17 December 2021** and preferably 4 weeks before this date.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from (signed/authorised) [CAG_Form_ReadyForSubmission]		
Data Protection Registration [Data Protection Registration]		
Other [Data Flows YHHN v2]	2	
Other [20CAG0149 CAT advice form v1.4 26.04.2019 YHHN]		
Other [Annual review PIAG 1 05(h) 2007]		01 March 2020
Other [PIAG 1-05 (h)2007 YHHN Register APPROVAL]		22 August 2007
Other [YHSG Letter of Support]		
Other [Letter Support Russell Patmore]		
Other [CAG email 25082020]		
Other [art-staff]		
Patient Information Materials [Adult Leaflet V13 May 2020]	13	
Patient Information Materials [AdultConsent V13 May 2020]	13	
Research protocol or project proposal [YHHN Protocol version 5]	5	
Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [Signed Caldicott Letter]		05 December 2018
Written recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [CAG_Application_Letter_of_Support_UoY]		19 November 2020

Membership of the Committee

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

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

Kathleen Cassidy
Confidentiality Advisor

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:	leedswest.rec@hra.nhs.uk approvals@hra.nhs.uk

Confidentiality Advisory Group meeting attendance
03 December 2020

Members present:

Name	
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Ms Sophie Brannan	CAG member
Dr Patrick Coyle	CAG vice-chair
Mr. Myer Glickman	CAG member
Dr Simon Kolstoe	CAG member
Dr Harvey Marcovitch	CAG member
Ms Diana Robbins	CAG member
Mr Marc Taylor	CAG member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

Standard conditions of support

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

The applicant and those processing the information 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.

6. Activities remain consistent 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.