



Northern Ireland Cancer Registry Research Access Policy

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1. Introduction

The Northern Ireland Cancer Registry (NICR) is located in the Centre for Public Health, Queen's University Belfast and is funded by the Public Health Agency for Northern Ireland. The Registry is responsible for the production of Official Statistics on cancer incidence, prevalence and survival in Northern Ireland and provides evidence to help inform decision making about cancer services.

The NICR has collected data on all cancer diagnoses (including non-melanoma skin cancers) from 1993. The quality and completeness of the data held by the NICR is regularly assessed with data quality indicators (performance indicators) submitted to the United Kingdom Association of Cancer Registries annually on the timeliness, quality and completeness of data. The performance indicators for Northern Ireland are available here <http://www.qub.ac.uk/research-centres/nicr/CancerInformation/data-quality/>

In addition to cancer diagnosis the NICR also contains information on some pre-malignant conditions. These databases have been compiled by research groups and have a separate data access policy, see Appendix 1.

One of the primary roles of the NICR is to provide a basis for undertaking population based research with the aim of improving the experience of patients and reducing the burden of cancer. The cancer registry can help answer research questions by:

- **Undertaking analysis of routine registry data to answer a specific question:** The cancer registry holds data on patient demographic characteristics, disease characteristics, clinical information including co-morbidities and treatment.
- **Linking to other datasets:** The registry data can be linked to other data sources to allow follow-up of cancer patients. Previous examples include linkage to the Honest Broker Service and Northern Ireland Biobank.
- **A sampling frame:** The registry holds details on all patients known to have a diagnosis of cancer in Northern Ireland and has up-to-date information on their vital status. The registry can therefore help researchers establish population-based sampling frames for research studies, including surveys.

All research must be undertaken in compliance with the NICR Confidentiality and Data Protection Policy. The NICR has ethical approval from the Office for Research Ethics Committee Northern Ireland (OREC-NI). This covers the collection of data on cancer patients and patients with certain pre-malignant conditions for official statistics, audit and research purposes. Separate ethical approval is still required for certain research projects.

2. Data Items Available

A list of data items collected routinely by the NICR is available for researchers to review, Appendix 2. Please note that this information may not be available or fully complete for all cancer patients.

3. Access

Access to NICR data is governed by the NICR Information Transfer and Release policy which is part of the NICR Information Security Management System, certified to ISO 27001 security standards. The policies are available for your inspection upon request.

3.1 Who can access NICR data for research purposes?

Researchers can be granted access to NICR data and will be classified into 4 groups:

1. Northern Ireland-based researchers from academia and healthcare.
2. Academia and healthcare researchers outside Northern Ireland but within the United Kingdom.
3. Academia and healthcare researchers outside the United Kingdom.
4. Commercial companies

Variations in the availability of data and data transfer arrangements will apply depending on the listing above.

3.2 Charges

The NICR charging policy is implemented when researchers require data or new analyses to be conducted outside of the production of the Official cancer statistics for Northern Ireland. This is based on a cost recovery model with reduced costs for academic and healthcare researchers. Further details of the charging policy can be found at this [link](#).

Costs for **academic and healthcare researchers** are broken down as follows*: (VAT if applicable is additional to these)

- Extraction fee: £500 plus staff time.
- Data linkage via Health & Care number (HCN): £500
- Data linkage where HCN is unavailable (includes manual review of matches): £700 for less than 1,000 records, £1000 for 1,000 to 4,999 records, £1500 for 5,000 or more records.
- Use of facilities - per request per year: £500
- Staff time will be charged at the full costs per hour to include salary, NI, pension, overheads etc.

Costs for **commercial companies** will be charged at £378 plus VAT per hour based on the projected time to complete the query once an application has been accepted. Contractual agreements will need to be completed before work can commence.

* Subject to annual review (next review September 2019).

Notes:

- Costs need to be calculated on an individual study basis. No estimates can be provided without submission of a **NICR Data Enquiry Form** (Appendix 3); see process below.
- We do not charge **academic or healthcare researchers** for the time taken to discuss the exact information requirements, to determine whether we hold the information requested or for the time it takes to decide whether the information is available and can be released.
- For **commercial companies** we charge a fee of £378 plus VAT per hour for the time taken to discuss the exact information, to determine whether we hold the

information requested or for the time it takes to decide whether the information is available and can be released.

Grant Applications

If researchers would like costings for grant applications they must submit a **NICR Data Enquiry Form** (Appendix 3) request at least 20 working days ahead of the submission deadline. If the enquiry form is submitted with less than 20 days to grant submission the NICR cannot guarantee that costings will be provided on time.

Exemption to charges

The following data requests will normally be provided without charge:

- Data requests received from sources which provide data or funding to the NICR, e.g. PHA and hospital Trusts (provided that rules on patient confidentiality are maintained).
- Genetic requests.
- Data requests which take less than one hour.
- Data requests required for participation in International or European studies e.g. Eurocare, CONCORD, Cancer Incidence in Five Continents.

3.3 Process of Application for NICR data

All researchers (academic, clinical and/or commercial) wishing to access data from the NICR for research purposes must complete a **NICR Data Enquiry Form** (Appendix 3) which will be reviewed by at least 2 members of the NICR Research Advisory Group within 20 working days of submission.

The NICR Research Advisory Group comprises representation from NICR staff, Northern Ireland-based researchers and clinicians. Our Advisory Group will be listed on the NICR website. The purpose of this advisory group is to review all **full** research applications to the NICR to determine if they:

1. Use scientifically robust methodology
2. Are covered by the existing NICR ethical approval and/or GDPR regulations
3. Would be able to be completed by the NICR within the research study timeframe taking into account personnel and accommodation resourcing.
4. Have an appropriate research team with sufficient experience in epidemiological research.

Estimated costings will be provided but these will be subject to the complexity of the request. Please ensure that **all data items** needed are identified and rationale for use provided.

Research applicants will be informed by e-mail as to whether their application has been:

- Approved (for research grant applications this will be subject to obtaining funding)
- Approved subject to minor amendments
- Rejected with resubmission recommended.
- Rejected as inappropriate/not feasible.

The panel will meet every 6 months to review research applications submitted to the NICR, progress of research investigations, funding and the breadth and scope of applications. All

applications will be kept strictly confidential and the panel members will not discuss applications outside of the formal advisory group meetings.

3.3.1 Ethics

The NICR has ethical approval from the Office for Research Ethics Committee Northern Ireland (OREC-NI). This covers the collection of data on cancer patients and patients with certain pre-malignant conditions for official statistics, audit and some research purposes. Most applications for use of NICR data are covered under the existing ethical approval however some studies may require a separate submission to OREC-NI. Researchers will be informed of this when their application has been reviewed by the NICR Research Advisory group.

3.3.2 Appeals

If a research submission is rejected the NICR Research Advisory Group Chair can be contacted and the matter discussed on a case by case basis.

3.3.3 Amendments

Researchers who would like to amend their approved application (e.g. getting additional data items, using new statistical methodology) which do not alter the overall aim of the study should contact the NICR administrator. The application will need to be updated. A letter detailing the changes being made to the application including appropriate justifications should be submitted along with a clean and track changes copy of the initial application. This will be reviewed by members of the NICR Research Advisory Group within 10 working days to determine if the amendments are acceptable or if a new application is required. Any changes to the original application will be subject to additional costs as per the standard NICR cost recovery process. Amendments to existing protocols will be processed within 20 working days. Note that for more complex submissions the timeframe may be longer than 20 working days. A projected timeline will be provided to the Principal Investigator at the time of amendment approval.

4. Data Access

Research not requiring access to identifying individuals will be released following compliance with Standard Operating Procedure QUB-ADNICR-002 (aggregate statistical data). Researchers requiring access to information potentially identifying individuals must complete an Enquiry and Researcher Declaration Form.

Research requiring access to personal health records of patients:

a) The individual patient records held by the NICR are subject to a confidentiality undertaking between the clinician(s) in charge of the patient at the time of registration and the NICR and therefore clinicians may request information on their own patients Enquiry and Researcher Declaration Form to be completed. If access is required by a researcher other than the treating clinician then, the approval of the treating consultant(s) must be obtained by the applicant before the research commences. This requires completion of an additional form. For requests that require release of historic data where treating clinicians may have left their position or for requests that require release of data relating to many clinicians it may not be possible to attain the signatures of all appropriate individuals. The decision to approve data release can be taken by the chair of the relevant multi-disciplinary teams that oversee the clinicians work.

- b) If the applicant is not medically qualified, they must obtain a further signature from a medically qualified colleague who will be responsible for the confidentiality of the information supplied. The NICR will then provide a list of consultant(s) clinically responsible for the data. The applicant must then seek completion of the appropriate forms by each clinician involved. Only then will the NICR release the data to the request applicant.
- c) If the research involves contacting the patient this must be done with eligibility confirmed by patient's clinicians i.e. Consultant or GP prior to patient contact. Invitation letters to patients should have a return address which does not mention 'cancer' and "To be opened by addressee only" on the outside of the envelope. This type of research study would require separate ethical approval.
- d) Where Ethical Committee approval is required, an approach must be made to the relevant Ethical Committee. Once approval has been given, written confirmation of this must be sent to the NICR. The NICR Director/Data Guardian would be pleased to advise if Ethical Committee approval is required.
- e) The data provided by NICR can only be used for the research purposes specified, and it must be impossible to identify any individual patient record in reports of the research.
- f) All reasonable precautions must be taken to ensure that the personal information does not fall into unauthorised hands. All copies of the information must be destroyed by a date specified by the Registry when the research is finished or abandoned. The Registry will offer practical guidance to applicants on dealing with the disposal of information.
- g) Transfer of data from outside the UK must not be made without the authorisation of the Director*. Such authorisation will generally only be given in respect of transfers to countries that are signatories of the European Convention of Data Protection or have been designated by EEC as meeting safe harbour privacy principles.

* Changes to the provision and transfer of data to European countries may change after the United Kingdom leaves the European Union.

4.1 Training

All researchers who will be accessing individual level data will be required to complete training regarding Registry and data security and handling and will be issued with a NICR badge dependent on the level of data access that they require (Amber for anonymised data, Red for identifiable data). Researchers must have completed all training (including any necessary training updates) before being given access to NICR data.

4.2 Computer Facilities

Hardware

Anonymised data: Researchers working with individual level data in an anonymised format in the NICR have access to 3 computers within the Amber zone in the NICR. Access to these computers can be booked through the NICR administrator.

Identifiable data: In some circumstances researchers may need access to identifiable individual level data. In this instance researchers will need a red access badge. At present the NICR has 3 computers available within the Red zone in the NICR. Note: these computers do not have access to the Internet.

Software

NICR computers have access to Microsoft Excel, SPSS (Version 25) and Stata (Version 15) for analytic purposes as well as Microsoft Word, PowerPoint and Publisher. Researchers who require any additional software packages to be downloaded to the computers should contact the NICR administrator in the first instance.

4.3 Data outputs.

If a researcher is working in the Amber areas and would like to take outputs from the Registry these must be reviewed by an allocated member of NICR staff. Currently given the number of data requests the NICR are implementing a maximum **10 working day turnaround** time on output clearance and any analytical queries researchers may have. Most will be facilitated in much less time.

Researchers are not permitted to take any data outputs from the Red areas. Memory sticks and mobile phones must be left securely in the NICR office when researchers access this area. If researchers have analytic code that you would like to use on these computers or take out from these computers this is subject to the same output clearance procedure outlined above. This is to ensure no identifiable data leaves the NICR.

5. Reporting results to the NICR and publications

5.1 Feedback Reports

All researchers will be required to complete an End of Research Investigation Report form as per the end of study date on the initial application. **Note:** Researchers will not be allowed to submit any new applications for access to NICR data if they do not complete the End of Research Investigation Report form.

5.2 Publication policy

The Principal Investigator(s) should be included on any resulting publications. Should a NICR representative be consulted with regards to collating data, data analysis and/or interpretation of data they should be consulted regarding authorship on any resultant manuscript. Please note that all written reports (including posters and presentations) using NICR data should be sent to the NICR pre-submission. This is for tracking and disclosure purposes to see how NICR data is being disseminated. A link to any published article using NICR data will be included on the NICR website.

5.1.1 Acknowledgements

The NICR should be acknowledged on any documentation produced using NICR data using the following statement:

“This research has been conducted using data from the Northern Ireland Cancer Registry under application number (xxxxx). However, the interpretation and conclusions of the data are the sole responsibility of the author(s). The author(s) acknowledge the contribution of the NICR staff in the production of the NICR data. Like all Cancer Registries our work uses data provided by patients and collected by the Health service as part of their care and support.”

5.1.2 Funding

The statement will vary depending on the database utilised but should be in the following format:

“The (database) was funded by (funder information). The Northern Ireland Cancer Registry was funded by the Public Health Agency for Northern Ireland. The funding bodies had no role in the study design and all researchers involved in this study are independent of the funding bodies.”



Pre-malignant Disease Register Access Agreement

The Northern Ireland Cancer Registry holds information on pre-malignant conditions under ethical approval granted (15/NI/0203) from the Office for Research Ethics Committee Northern Ireland (ORECNI).

The registry captures routine data on pre-malignant conditions in Northern Ireland, however only the following datasets have been constructed with fully cleaned data:

- Barrett's Oesophagus Register – The Northern Ireland Barrett's oesophagus Register, established by the late Professor L Murray, is one of the largest population-based registers of Barrett's oesophagus worldwide. It includes information on >13,000 incident diagnoses in Northern Ireland since 1993 and data are currently available up to end 2010 (PI: Dr Helen Coleman).
- Colorectal Polyp Register - The Colorectal Polyp Register includes information on all polyp diagnoses from 2000 to 2005 in Northern Ireland (PI: Dr Anna Gavin).
- Endometrial Hyperplasia Register – The register includes details of all patients diagnosed with endometrial hyperplasia from 2008 to 2014 (PI: Dr Helen Coleman)
- Monoclonal Gammopathy of Undetermined Significance (MGUS) Register - Data for the register have been collected from 1993 to date from all Health and Social Care Trusts (with the exception of some historical data pre 2008 from BHSCT) and is in the process of being cleaned (PIs Dr Lesley Anderson & Dr Charlene McShane).

Access to the pre-malignant registers are governed by the NICR Information Transfer and Release policy which is part of the Northern Ireland Cancer Registry Information Security Management System, certified to ISO 27001 security standards. The policies are available for inspection upon request. If a researcher wishes to gain access to the data from any of the pre-malignant registries the **"Pre-malignant Disease Register Request Form"** attached should be completed and submitted to nicr@gub.ac.uk. Once received, the Northern Ireland Cancer Registry will assess the request including the availability of the data items requested and the level of data required (i.e. Aggregated, potentially identifiable, record level etc). If approved they will then provide a researchers with an estimate of the administrative fee charges to access the data (if applicable). For the most up-to-date version of the Administration fee recovery charges click this [link](#).

If a researcher wishes to pursue the application the "Pre-malignant Disease Register Access Agreement Form" will be passed to the Pre-malignant disease register Principal Investigator(s). The Principal Investigators will have 20 working days to review the initial application and provide a decision to the Northern Ireland Cancer Registry regarding whether or not access may be granted. The Principal Investigator may get in contact with the researcher if they require clarification or have questions relating to the application. Please note that each Principal Investigator will consult with the broader research team who constructed the datasets prior to any decisions being made.

Once access is agreed the NICR will provide the researcher with a standard NICR Data Access Form. Upon receipt the request will be dealt within 20 days unless complex in which case NICR staff will provide a projected timeline. Standard Operating Procedures and security protocols will need to be followed to access the data. This will include working in the NICR for data analysis on anonymised

datasets. The applicant is advised that the Principal Investigator(s) and the Northern Ireland Cancer Registry should be kept updated with regards to the progress of the research and provided with a final written report upon completion.

Publication policy

The Principal Investigator(s) should be included on any resulting publications. Should a NICR representative be consulted with regards to data analysis and/or interpretation of data they should be consulted regarding authorship on any resultant manuscript. Please note that all written reports using NICR data should be sent to the NICR pre-submission. This is for tracking purposes to see how NICR data is being disseminated.

Acknowledgements

The NICR should be acknowledged on any documentation produced using NICR data using the following statement:

“This research has been conducted using data from the Northern Ireland Cancer Registry under application number (xxxxx). However, the interpretation and conclusions of the data are the sole responsibility of the author(s). The author(s) acknowledge the contribution of the NICR staff in the production of the NICR data. Like all Cancer Registries our work uses data provided by patients and collected by the Health service as part of their care and support.”

Funding

The statement will vary depending on the database utilised but should be in the following format:

“The (database) was funded by (funder information). The Northern Ireland Cancer Registry was funded by the Public Health Agency for Northern Ireland. The funding bodies had no role in the study design and all researchers involved in this study are independent of the funding bodies.”



Pre-malignant Disease Register Request Form

Please submit form to nicr@qub.ac.uk.

DETAILS OF APPLICANT

Name:	Title:
Position:	Address:
Telephone No:	
Email:	
Title of Study:	
Aims and Purpose of Study*:	
Brief background rationale to Study*:	
Brief proposed Methodology*:	
Details of Information Required:	
SIGNATURE OF APPLICANT:	
DATE:	

* A full research protocol must also be submitted.



Routine Data Items Available

• Patient

- Health and Care Number¹
- Surname(s) ¹
- Forename(s) ¹
- Date of birth¹
- Sex
- Marital Status
- Current address¹
- Current postcode¹
- The following may be derived from postcode:
 - Geographical variables¹ such as:
 - Health and Social Care Trust
 - Parliamentary Constituency
 - Local Government District
 - Electoral Ward
 - Rural or urban location
 - Super Output Area,
 - Census small Area
 - Deprivation Quintile
- Comorbidities
- General Practice code
- Deprivation (derived from postcode of residence at diagnosis)
- Date of death¹
- Fully coded causes of death from the death certificate
- Coded underlying cause of death

• Tumour

- Tumour ID number
- Tumour site (ICD-10)
- Tumour cell type (ICD-O2 or ICD03 available)
- Behaviour (Malignant, Benign, In-situ or Uncertain)
- Date of diagnosis
- Age at diagnosis
- Address at diagnosis¹
- Postcode at diagnosis¹
- Basis of Diagnosis (Histology, CT scan, death certificate etc)
- Tumour Grade (site-specific grade e.g. Gleason for prostate cancer, WHO for brain tumours)
- Tumour laterality
- Tumour size
- Pathology report number
- Pathology report text
- Stage at diagnosis (Dukes, FIGO, Clarkes etc.)

- TNM staging to include: clinical, pathological and a combined registry staging
- Molecular data. Currently collect:
 - ER, PR and HER2 status for breast tumours
 - PSA level in prostate cancer
 - HPV 16 for oropharyngeal tumours
- **Treatment**
 - Type of treatment (surgery, radiotherapy, chemotherapy)
 - Date of treatment
 - Consultant code
 - Surgical procedure code (OPCS4 code)
- **Death**
 - Date of death
 - Fully coded causes of death from the death certificate
 - Coded underlying cause of death

Other information can be obtained from clinical notes but will require note review. These include, but are not limited to:

- Smoking status
- Alcohol
- Body mass index
- Presenting symptoms
- Route to diagnosis
- Co-morbidities

Through linkage with the Honest Broker Service

(<http://www.hscbusiness.hscni.net/services/2512.htm>) :

- Prescription data (Enhanced Prescribing Database)
- Maternity data (Northern Ireland Maternity System NIMATS)

¹Only released when conditions set out by the NICR's ethical approval are met



Northern Ireland Cancer Registry Data Enquiry Form

Name and title of applicant:	Position:
Address:	Telephone: Email:
Title of study:	
Aim and purpose of study ^a :	
Details of information required (list each data item, appending additional pages if necessary) ^b :	
If there is a deadline for receipt of information, please give reason and date:	

^a Please submit any associated study protocols, ethical agreements etc.

^b Do not include any identifiable patient information on this form

Please return the completed form to:
Information Governance, N.Ireland Cancer Registry, Centre for Public Health, Mulhouse Building,
Grosvenor Road, Belfast, BT12 6DP nicr@qub.ac.uk

Flow diagram

