

Data security and confidentiality in the National Cancer Registry

General policy and procedures for release of data

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| Version | 1.1 |
| Revision date | 04/04/2016 |
| Revised by | Harry Comber |
| Date approved by Board |  |

Contents

Contents

[1 Introduction 1](#_Toc444526816)

[2 Summary of policy on data release 2](#_Toc444526817)

[2.1 Confidential data 2](#_Toc444526818)

[2.2 Restricted data 2](#_Toc444526819)

[2.3 Unrestricted data 2](#_Toc444526820)

[3 General Principles of Confidentiality in the National Cancer Registry 3](#_Toc444526821)

[3.1 Definitions 4](#_Toc444526822)

[3.2 Operation of the Registry 5](#_Toc444526823)

[3.2.1 Data collection. 5](#_Toc444526824)

[3.2.2 Processing of Information. 5](#_Toc444526825)

[3.2.3 Data reporting and analysis. 5](#_Toc444526826)

[3.2.4 Confidentiality relating to employee records 6](#_Toc444526827)

[4 Procedures for release of National Cancer Registry data 7](#_Toc444526828)

[4.1 General guidelines on information release 7](#_Toc444526829)

[4.2 Types of information which might be requested 8](#_Toc444526830)

[4.2.1 General information 8](#_Toc444526831)

[4.2.2 Aggregate information 8](#_Toc444526832)

[4.2.3 Individual-level data 8](#_Toc444526833)

[4.3 Requesting data 10](#_Toc444526834)

[4.3.1 Unrestricted data 10](#_Toc444526835)

[4.3.2 Restricted data 10](#_Toc444526836)

[4.3.3 Confidential data 13](#_Toc444526837)

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# Introduction

This document sets out the broad principles and practice relating to data security and confidentiality within the Irish National Cancer Registry. It describes

* the principles underlying these policies
* procedures for the release of data
* methods of achieving data security and confidentiality of data

# Summary of policy on data release

The Registry will supply data in response to any reasonable or bona fide request, provided that complying with the request does not conflict with our obligations of confidentiality or with those under the Data Protection Act, 1988 (amended 2003). The use of the data by the applicant must be also consistent with the Data Protection Acts. Data will be anonymised where feasible, and, if not, consent must be obtained.

If the amount of data analysis involved is extensive and/or the data is requested for commercial purposes, a fee may be payable to cover our costs. We attempt to respond to all requests within two working weeks of receipt and should be able to reply to most within a week.

The Registry classifies the data held into three categories: confidential, restricted and unrestricted.

## Confidential data

**Confidential data** is any **sensitive personal[[1]](#footnote-1)** information (see section 3.1.2 for definitions) relating to an identified or identifiable[[2]](#footnote-2) person, whether alive or dead. This definition extends to deceased persons many of the protections available under the Data Protection Acts. Data, by which the persons concerned can no longer be reasonably identified, are not considered as personal data.

**Confidential data held by the Registry on living persons will be released only with the written explicit consent of the data subject.** Confidential data may be provided for research or audit purposes to a hospital in which the patients were treated or investigated and which had a cancer database at the time of registration. Patients should have been aware that their data was stored on such a database and that the hospital might share data with the National Cancer Registry. Requests for this confidential data must be made by, or on behalf of, the Data Controller (the hospital or HSE CEO) and the request must be the basis of a data processing agreement (see pp 18-19) between the hospital (or HSE) and the National Cancer Registry. Requests for confidential data must be made using a standard application form, and a declaration on use must be signed. All requests for confidential information must be approved by the Director. Processing and release of confidential data relating to living persons is subject to the Data Protection Acts.

## Restricted data

**Restricted data** is any data, which is not confidential, but the use and dissemination of which is subject to certain restrictions by the Registry. Processing and release of restricted data is not subject to the Data Protection Acts but is governed by the policies of the National Cancer Registry. Any person requesting restricted information must do so in writing, either by post, fax or email[[3]](#footnote-3).

## Unrestricted data

All information not classified as confidential or restricted is freely available to any member of the public on request. However, the Registry reserves the right to refuse requests for information, or to charge for the service, if, in the Registry’s view, requests involve disproportionate effort, are not made in good faith, have a malicious intent or are excessive in number.

**This document does not apply to requests for information under the Freedom of Information Acts, which should be made to our Freedom of Information Officer, Ms Geraldine Finn, at 021-4318014 or to g.finn@ncri.ie.[[4]](#footnote-4)**

# General Principles of Confidentiality in the National Cancer Registry

Confidentiality in the use of personal data in medical research is governed both by the ethical guidelines of the medical profession[[5]](#footnote-5) and by the provisions of the Data Protection Acts, 1988 and 2003. Preservation of patient confidentiality has always been one of the highest priorities of the Registry. Patients, and their doctors, should be assured that their privacy, dignity and autonomy are central to the operations of the Registry. At the same time, the statutory duty of the Registry to “identify, collect, classify, record, store and analyse information relating to each newly diagnosed individual cancer patient and…each tumour which occurs” places an obligation on us to use the information gathered in a way which maximises its benefit for the public good. For the Registry to withhold information which could be used to reduce the burden of cancer would be, at best, a waste of public funds and, at worst, unethical.

The principles of confidentiality must apply, not only within the Registry, but also to any data released by it, whether for public information, or to individual researchers. In particular, the Registry must take care not to publish data, or to provide it for publication by others, in a way that would allow any individual to be identified, even indirectly. The obligations of the Registry to deceased persons and their families are given as much consideration as those of the living. Against this need to protect the rights of the individual must be balanced the value of accurate cancer registration data in assessing the causes, treatment and outcome of cancer. [[6]](#footnote-6) [[7]](#footnote-7) [[8]](#footnote-8)

The Board of the Registry, in carrying out its functions, has adhered to the following principles:

a. Permission for access to confidential information on living persons, which is held by the National Cancer Registry, must be given by the patient, except where this information is to be used in the course of his/her clinical care.

b. No disadvantage, harm or distress may be caused to the patient by this access;

c. Appropriate safeguards must be in place to preserve the confidentiality of the information in our custody;

d. Reports of our work must not contain information which would remove, without consent, the anonymity of a patient or health care professional;

e. The Registry has a duty to maximise the use of information in its possession to the benefit of all patients.

The National Cancer Registry holds data under two broad headings: registration data (including linked datasets), collected as part of the Registry’s routine data collection; and research data collected in defined research studies. Collection of registration data is covered by the Health (Provision of Information) Act and does not require consent. Information collected in research studies is collected and used with consent, and its uses are governed by that consent. The Registry procedures described here with regard to data release pertain only to the registration data, unless specifically noted. Data given with consent will be released only as allowed by the consent. Procedures with regard to data security apply to all data.

Successful cancer registration requires that the Registry uses identifiable information, for a number of reasons:

a. Information on a single cancer often comes from a variety of sources. This duplication of information would inevitably lead to multiple registrations of the tumour, and a gross over-estimation of the rate of incidence of cancer, unless some method were available for linking all information on the same individual.

b. Information on outcome, and particularly on survival, is essential to the operation of the Registry, and links between registrations and death certificates can only be achieved by the use of some type of personal identification.

c. The Registry can carry out assessment of the success and coverage rate of screening programmes only if individuals screened can later be identified if they develop cancer.

d. Cancer registries may also contribute to medical research by allowing researchers to identify (with consent from the patient and appropriate ethical safeguards) individuals with cancer for the purposes of case-control studies of cancer aetiology, and by helping with the recruitment of individuals to properly conducted clinical trials of cancer treatment. Because these individuals may have been treated by a number of physicians in different institutions, the Registry may offer the only method of allowing their identification and follow up.

e In Ireland, as there is no national identity number or other means of identifying an individual other than through a combination of name, address and date of birth, the Registry must hold these items of personal information on each person registered.

The principles of confidentiality can be reconciled with the functions of the Registry by the adoption of a comprehensive code of practice governing the acquisition, processing, storage and release of identifiable patient data. Where doubt exists as to the appropriateness of a particular line of action, this code of practice must have as its highest priority the protection of the rights of the individual patient. As well as guidelines for the use of data within the Registry, this code of practice must also include guidelines on the use of Registry data by individuals outside the Registry, and should also protect the rights of the dead as well as living persons.

## Operation of the Registry

### Data collection.

The Registry obtains data on patients with cancer from a variety of sources:

#### Pathology Laboratories.

The majority of notifications come initially from pathology reports. Similar notifications may be received from haematology, cytology and, on rare cases, radiology departments. These notifications rarely contain sufficient information for a full registration, and the registration is completed by reference to the patient's medical records.

#### Medical Records.

A systematic search of medical records from appropriate departments, such as radiotherapy and oncology, yields the names of patients who had not been notified through pathology reports. The medical records contain all the information necessary for registration. Other sources based on the medical records (e.g. Hospital Inpatient Enquiry (HIPE), radiotherapy, pharmacy, oncology and multi-disciplinary team meeting records) may also be used as sources of data.

#### Death Certificates.

The diagnosis of cancer may be initially notified to the Registry from death certificates, which are supplied by the Central Statistics Office. If the patient died outside hospital, the physician certifying the death is then contacted and can either give the information necessary for a full registration or can allow the patient to be identified and the medical records retrieved. Otherwise the death certificate is followed up by the tumour registration officer responsible for the hospital in which the patient died.

#### Other Registries.

Notifications, updates or treatment of patients normally resident within the Registry area are sometimes received from registries outside of Ireland, mainly from the Northern Ireland Cancer Registry and from registries in England, Scotland and Wales.

### Processing of Information.

Each notification is checked against the existing Registry database, to see if the cancer has already been registered. Records can usually be matched on the basis of full name, address and date of birth. If no previous entry exists for the cancer, it is registered, and the record added to the database. Registrations are made by Tumour Registration Officers, who are qualified nurse and permanent employees of the Registry, and who have signed an undertaking to safeguard the confidentiality and security of all the information to which they have access. All phases of data collection, storage and transmission are protected by computer passwords and encoding of the data. Regular external and internal security reviews are carried out.

On arrival at the Registry central database, these registrations are again checked against the database for duplication. The people who do this checking also sign the undertaking mentioned above.Patient name, date of birth and address are removed from the database before it is used for analysis, and access to identifiable information is limited to a small number of named persons within the Registry. For data processing purposes, identifiable information is essential for elimination of duplicate registrations, for follow-up of patients through death certificates and linkage to hospital and HIPE databases, cancer screening and PCRS. Patient addresses are used to allocate cases to an electoral division of residence.

### Data reporting and analysis.

The procedures for data release are set out in more detail in section 4. The section below describes, in outline, the ways in which data is used by the Registry, including provision of data to third parties.

#### Statistical reports

The main use of the data is to produce regular statistical reports on cancer incidence, treatment and survival overall and for particular sub-groups of the population, broken down by cancer type. None of the data is presented in a way which could allow the identification of individuals.

#### Detailed reports

The Registry also produces, on request, specific analyses of the data for researchers and others. These analyses do not identify individuals, and are governed by safeguards with regard to the use of the data.

#### Release of non-identifiable data

The Registry provides aggregate or anonymised individual data for bona fide research purposes, provided this does not carry any risk of identification of any individual.

### Confidentiality relating to employee records

Personal and sensitive information is collected by human resources (HR) only where it is necessary for the HR function or any related activity. This information will normally be gathered directly from the individual concerned. At the time the information is collected the staff member will be advised whether or not the provision of the information is compulsory. One example of this is the information collected through the disability census each year.

# Procedures for release of National Cancer Registry data

The National Cancer Registry contains information on registrations of patients with cancer in Cork and Kerry from 1980 onwards and for the whole of Ireland from 1994. It is a valuable resource, available for use in epidemiological and clinical research, as well as the planning and evaluation of services. We welcome requests for information for research, planning and statistical purposes. The Registry also holds information collected as part of research projects but this, in general, is not available outside the specific project.

However, because of the sensitivity of much of the information we keep on file, we observe certain procedures with regard to the release of information. These procedures apply both to the supply of data by the Registry and to its subsequent analysis and publication.

The following section sets out the current guidelines for the release of registration data. If you would like more information on our procedures, or if you have some special data needs, the Director would be quite happy to amplify or clarify any of the information below.

## General guidelines on information release

The Registry will supply registration data in response to any reasonable or bona fide request, provided that complying with the request does not conflict with our obligations of confidentiality or with those under the Data Protection Act, 1988 (amended 2003).The use of the data by the applicant must be also consistent with the Data Protection Acts. Data will be anonymised where feasible, and, if not, consent must be obtained. In the great majority of cases, only anonymised data will be provided. Sensitive or confidential data can only be supplied under strict restrictions as set out below.

The Registry classifies the data held into three categories: confidential, restricted and unrestricted. This classification is based on the potential of the data to identify an individual, and not on the format (aggregate, individual) in which the data is provided. Requesters will be asked to complete a basic request form, the purpose of which is to ensure that all requests are responded to in a timely and accurate way. All data requests will be reviewed on receipt and classified as either restricted (and potentially confidential) or unrestricted. Vague requests, such as “information on breast cancer” cannot be dealt with and will be returned to the requester. Requests for restricted information will be followed up with the requester.

Any person requesting restricted information must do so in writing, either by post, fax or email[[9]](#footnote-9). Requests for restricted data (see section 4.3.2) must be made using the standard application form which is on the Registry website, and the attached declaration at the end of this form must be signed. Following receipt of this form, the Registry will decide whether the data requested is confidential; if this is the case the requester will be asked to modify the request or to obtain consent for data release.

If the amount of data analysis involved is extensive and/or the data is requested for commercial purposes, a fee may be payable to cover our costs. We attempt to respond to all requests within two working weeks of receipt and should be able to reply to most within a week. The Registry reserves the right to refuse requests for information, or to charge for the service, if requests are considered to involve disproportionate effort, are not made in good faith, have a malicious intent or are excessive in number.

The information available can be broadly classified as:

* general
* aggregate
* individual

## Types of information which might be requested

### General information

This describes the total number of cases broken down into broad categories, such as age band, sex, site or county. This information is of the same general level of detail as that published in the annual reports of the Registry and is also available on the Registry website at [www.ncri.ie](http://www.ncri.ie). However, the Registry must be identified as the source in any publication of the data. Requesters are encouraged to check if this information has already been made available electronically by the Registry before making a request.

### Aggregate information

Aggregate information is that which is analysed in greater detail than described above, at a level which is not routinely produced and published by the Registry, but which does not allow the direct identification of individuals.

In some cases—for instance, analysis of small geographical areas for uncommon cancers—individuals may be potentially identifiable. Information of this type is considered “restricted” and is subject to the principles and procedures as set out below under “Restricted data” (section 4.3.2). Aggregate information will be made available on tumours by site, by histological type, by age band, and for district electoral division or city ward. Cross-tabulations of this data will also be made available, subject to the principles and procedures in “Restricted data” (section 4.3.2).

All requests for aggregate data must be made on the detailed application form, which is available on request or can be downloaded from our website www.ncri.ie.

### Individual-level data

Individual-level data may be either identifiable or non-identifiable. Identifiable data is always considered confidential, as the fact of registration implies a diagnosis of cancer and is considered to be “sensitive personal” data under the Data Protection Acts if the individual is alive.

Anonymised individual data carries no risk of identification of the individual and its use is not, in general, restricted. However, there is no clear division between identifiable and non-identifiable data. Some data items considered to carry a high risk of identification (e.g. name, address, identification number) are always considered confidential (see below). Others, such as date of birth, do not identify an individual if taken on their own, but have a high probability of doing so if combined with other data. Other information (e.g. occupation, electoral division of residence) has a very low potential for identification but this may occur through rare combinations of variables, or by linkage with other databases. Although this is unlikely in practice, the release of items with any potential for identification is routinely restricted by the Registry. Release of this data, while not requiring patient consent, is subject to the principles and procedures as set out below under “Restricted data” (section 4.3.2). If the Registry considers that there is a real risk of identification from the data requested, then the request must be modified or patient consent sought.

#### Personal (identifiable) data.

Data is considered by the Registry to be identifiable if it contains any of the following:

a. Patient’s name and/or full address

b. Date of birth

c. Hospital or other registration number

d. GMS, PPS or other identifying numbers

e. If the unit of analysis is sufficiently small to allow the identification of individual patients, using other data available to the requester.

**Identifiable information held by the Registry is always confidential, as it carries the implication of a cancer diagnosis.**

#### Identifiable information on deceased patients

Information from death certificates is obtained by the Registry from the Central Statistics Office and the General Register Office. If an individual is deceased, permission to access information on cause of death must be obtained, under the Vital Statistics Acts, from the Registrar General at the Department of Social Protection. The date of death is not considered to be confidential information and is available on request.

Other identifiable information held by the Registry on deceased persons will be released (unless the individual has previously indicated that they wish to withhold consent) only if approval has been obtained by the applicant from an appropriate Ethics Committee. [[10]](#footnote-10)

#### Identifiable data for genetic counselling.

The National Cancer Registry, while wishing to facilitate people having genetic counselling, takes as its primary principle the confidentiality of cancer patients, whether living or deceased. Information concerning living cancer patients will not be released without written consent.

Requests for Registry information from recognised[[11]](#footnote-11) genetic counselling clinics regarding suspected cancer diagnoses in **living** family members, related to a proband undergoing counselling, should be accompanied by a dated signed consent form obtained from each family member (or a legal guardian) about whom information is sought. The consent form should permit the release, to the genetic counselling clinic, of information relating to their cancer diagnoses from medical records. Information on deceased cancer patients can be provided to recognised genetic counselling services working within a clear and published set of ethical rules.

Information cannot be released to any genetic counselling services in Ireland which do not conform to the provisions of the Disability Act.

## Requesting data

### Unrestricted data

Data which, in the opinion of the Registry, has no potential to identify an individual, is freely available (subject to certain conditions) from the Registry, as either anonymised records or aggregate data.

The Registry classifies the data held into three categories: confidential, restricted and unrestricted. This classification is based on the potential of the data to identify an individual, and not on the format (aggregate, individual) in which the data is provided.

Requesters will be asked to complete a basic request form, the purpose of which is to ensure that all requests are responded to in a timely and accurate way. All data requests will be reviewed on receipt and classified as either unrestricted or restricted.

#### Procedures for requesting unrestricted data

The majority of requests will be for unrestricted data, which is considered by the Registry to have no potential to identify an individual. This is the type of data routinely published by the Registry or available on our website. This data can be obtained from the Registry by an email or telephone request. Requesters will be asked to complete a basic request form, the purpose of which is to ensure that all requests are responded to in a timely and accurate way.

If, in the opinion of the Registry, any of the data requested has the potential to identify an individual, it will be dealt with as restricted data.

### Restricted data

Restricted data is any data, which is not personal data, but is

1. Anonymised or aggregate data which applies to a small and/or potentially identifiable group of individuals (for instance a small geographical area, where other information such as age or occupation are also given).
2. Anonymised or aggregate data with a level of detail (e.g. electoral division of residence) which might, under certain circumstances, allow an individual to be identified.
3. Data, the publication or dissemination of which could cause distress, loss or embarrassment to any individual or institution.

A very large number of possible combinations of data fields is available from the Registry, and these may be requested for many different subsets of the population. It is therefore impossible to set out definitive rules to cover all of these eventualities; each request will need to be dealt with on its merits. In cases of uncertainty, the opinion of the Data Protection Commissioner will be sought.

#### General conditions of use of restricted data

Unlike confidential data, there is no absolute prohibition on the release of restricted data, but its release is subject to some conditions. The Registry is subject to Freedom of Information provisions, so any “document” produced by us could potentially be demanded by any member of the public. The following conditions apply to the release of restricted data:

1. The probable benefits of releasing the data must outweigh any potential for damage.
2. Requesters must undertake:
3. to use the data only for the purposes specified.
4. not to pass it to anyone else.
5. not to link it to other data unless this was specified in the original request, or is specifically agreed by the Registry at a later time. The National Cancer Registry will have to give consent for the data to be linked with any other databases.
6. not to attempt to identify, any individual, family or dwelling, or to publish the data in a way which would allow any individual, family or dwelling to be identified, either directly or by linkage with other data.
7. to take every precaution to avoid the identification of individuals or institutions in any publication.
8. to delete or destroy the data (all paper and electronic copies) at an agreed date and to inform the Registry that this has been done (a note should be kept of this data at the time of request and a reminder automatically set up).
9. users of the data must ensure that, in complying with the above conditions, they also observe the relevant provisions of the Data Protection Acts and the Freedom of Information Act.
10. Data should not be released to users outside the State without the permission of the Director (or other authorised person). The permission of the Data Protection Commissioner may be required for some transfers, especially outside the EU.

#### Procedures for requesting restricted data

If the data requested appears to be potentially identifiable, requesters will be asked to return a detailed request form (which is on our website). One copy of this form will be kept by the Registry and the other returned to the requester. All requests should specify:

1. The scope of the dataset (e.g. years covered, sites, geographical area, cases, deaths or treatments).
2. The variables required.
3. The level of specificity for each variable (e.g. year of birth or five-year groups).
4. The purpose of the study/audit/report.
5. In general terms, the level of analysis proposed.
6. The title and job description of the requester, and the names of all other persons who will have access to the data.
7. Where hospitals and/or consultants are being identified, the status of the person giving permission for the data to be released.
8. A record of the request (the request form), and a copy of the data sent out, should be kept (and should be relatively easy to retrieve) for Freedom of Information purposes.
9. For confidential data, the information to be given to the patient and a copy of the consent form. If the patients are deceased, evidence of ethical approval will also be required.

Following receipt of the request, a member of Registry staff may contact the requester, to discuss the exact data requirements. In many cases, this will allow us to release data which meets the requirements of the requester but is not potentially identifiable. The general principles which will apply, with regard to safeguarding confidentiality are:

1. Aggregated or cross-tabulated data will be offered in preference to individual-level data. In instances where either patient case numbers or denominator data is small, with a resultant potential for individuals to be identified, data may be aggregated over a number of years – e.g. data provided in 5 year period blocks (year of diagnosis 1994-1998, 1999-2003 etc.)
2. If the risk of identifying an individual patient is high, either directly or by linkage to other data in the possession of the requester, the data will be treated as confidential and the request denied unless patient consent is given or the requester has clinical responsibility for the patient.
3. If data is being given out as individual records (microdata) or where the denominator population is small, variables will be re-coded to the lowest level of specificity which will serve the purpose of the study. Information with the potential to identify individuals will be grouped to prevent identification, as follows:
4. **Precise dates (birth, death, diagnosis).** It is rarely necessary for researchers to have exact dates. In general, age will be provided aggregated into five-year age groups, but year of birth may provided if there is a specific need. Year of incidence (diagnosis) will be sufficient for most purposes, but if survival is being calculated, month of diagnosis (and of death) may be provided. If this is not sufficient, derived data (e.g. survival in days, rather than precise dates of incidence and death) will be offered, but care is needed to ensure that this is done appropriately and correctly. In some circumstances, with agreement of the Director, precise dates of diagnosis and of death may be provided.
5. **Full morphology codes**. These are not usually provided; three character (e.g. 804) codes will be given. Where full codes are essential for the work proposed, less common codes will be grouped to avoid potential identification.
6. **Full treatment codes**. Unless specifically requested, only codes of “surgery”, “radiotherapy” etc. will be given.
7. **Occupation** will always be aggregated to the second digit (of the 3 digit UK SOC90 standard occupational classification code) if age is also given.
8. **Local area of residence (Electoral Division, ED or Small Area).** A single case occurring in an ED is not in itself a reason to refuse the data, as long as the other information given (e.g. age, occupation) is not sufficient to identify someone. It is the size of the denominator population, not the number of cases, which carries the risk of identification. However, care must be taken, as some EDs have very small numbers of residents in particular age groups and the identification of individuals in these may be possible. Individual level data will never be released for the EDs described by the Central Statistics Office as “confidential”. These change with each census, and are always combined with a neighbouring ED.
9. **Data identifying a hospital.** It is not difficult, using other published data, to identify hospitals by workload, so all such data is treated as restricted.

Data on hospital activity, or which could be used to infer hospital activity, will be given out only if:

1. Permission is given by, or on behalf of, the chief executive of the hospital; or
2. The request is made by, or on behalf of, the HSE, the Department of Health and Children or the Health Information and Quality Authority for a publicly funded hospital; or
3. The request is made by a body or individual with a legal right to the data; or
4. Permission is given by a hospital medical consultant acting on behalf of a specific group of consultants or specialties within the hospital.
5. **Data identifying an individual health care worker.** In general, data which could identify the workload or patterns of care provided by an individual health care worker should not be released without the written consent of that individual; consent should always be sought. If consent is refused, information may be released (following consultation with the Data Protection Commissioner) to
6. Any body or individual with legal right to the data; or
7. The HSE, the Department of Health and Children or the Health Information and Quality Authority in respect of activity in a publicly funded hospital.

Some restrictions on data use will apply (see section 4.3.3).

If the data request cannot be modified to remove the potential for patient identification, procedures with regard to release of confidential data (section 4.3.4) will apply. Certain combinations of specific information (street address, date of birth, occupation to the third digit) when combined with less specific data, may be enough to identify an individual, and each request will be considered individually. If the risk of identifying an individual patient is high, either directly or by linkage to other data in the possession of the requester, the data will be treated as confidential. In cases of doubt, the Director, as responsible person under the Data Protection Act, will be consulted.

### Confidential data

**Confidential data** is any sensitive personal information relating to an identified or identifiable person, whether alive or dead.

Although the definition of “confidential” information used here is similar to that given for “sensitive personal” data in the Data Protection Acts, the Registry definition is extended to cover deceased persons, who are not covered by the Acts. This definition extends to deceased persons many of the protections available under the Data Protection Acts. However, for obvious reasons, the requirement for consent cannot be extended to deceased persons and so alternative safeguards are needed.

**Personal data** is data relating to a living individual who is or can be identified either from the data, or in conjunction with other information that is in, or is likely to come into, the possession of the data controller (Data Protection (Amendment) Act 2003).

**Sensitive personal data** includes data that identifies (a) the racial or ethnic origin, the political opinions or the religious or philosophical beliefs of the data subject,(b) whether the data subject is a member of a trade union (c) the physical or mental health or condition or sexual life of the data subject,(d) the commission or alleged commission of any offence by the data subject, or(e) any proceedings for an offence committed or alleged to have been committed by the data subject, the disposal of such proceedings or the sentence of any court in such proceedings. (Data Protection (Amendment) Act 2003).

**An identifiable person** is one who can be identified, either:

**a**. directly *or*

**b**. indirectly, in particular by reference to an identification number, or to one or more factors specific to his/her physical, physiological, mental, economic, cultural or social identity.[[12]](#footnote-12)

Data of such a type by which the person concerned can no longer be reasonably identified are not considered as personal

#### Procedures for release of confidential data

Confidential information is not released without patient consent, except to doctors with clinical responsibility for the patient, under the conditions set out in section 3.2.4.2.

**For informed patient consent** the patient must have been given, at a minimum,

1. a brief description of the uses to which the information will be put,
2. the names and affiliations of the researchers involved,
3. the interventions planned by the researchers (if any),
4. a clear statement that the patient is completely free not to participate without consequences
5. a clear statement that the patients may withdraw this consent at any stage, without consequences.

Consent should always be given in writing, but patients are given a contact address and telephone number if they wish to discuss any aspect of the research or consent further.

The general practitioner or an appropriate hospital consultant should be contacted prior to attempting to contact the patient, to check that the patient is alive, fit to give consent and aware of the diagnosis.

Confidential data may be provided for research or audit purposes to a hospital in which the patients were treated or investigated and which had a cancer database at the time of registration. Patients should have been aware that their data was stored on such a database and that the hospital might share data with the National Cancer Registry. Requests for this confidential data must be made by, or on behalf of, the Data Controller (the hospital or HSE CEO) and the request must be the basis of a data processing agreement between the hospital (or HSE) and the National Cancer Registry.

Confidential data should be accessible only to those named in the data processing agreement. Enquiries for the purposes of genetic counselling must also adhere to this principle.

Patient name or house/street address and identification numbers of any sort (including National Cancer Registry registration number, medical record number, pathology reference number) are always treated as confidential.

If an identification number is needed for each case, for quality assurance or other purposes, a substitute number will be supplied and a lookup table kept at the Registry.

In general, all requests for confidential data must be approved by the Director or a designated person in his absence; the request must meet the following minimum criteria:

1. the project will be of some clear benefit.
2. the data are essential for the purposes described.

#### General conditions of use of confidential data

1. Individual-level data (other than non-identifiable individual-level data as already downloadable from the Registry website) will be provided only when no alternative method of investigation is available, and if, in the view of the Director, the benefits to accrue from the data use outweigh any potential risks. Aggregated or cross-tabulated data will always be offered in preference to individual-level data.
2. The data user must work within a recognised institution of some standing (e.g. third level institution, health service organisation). All individuals who will have access to the data must be named.
3. Information which could identify a hospital or health care professional will normally require consent from the hospital or individual.
4. The data must be requested by, and released only to, the data controller in the relevant organisation
5. The data processing agreement should indicate
   1. arrangements for storage, security and access to the data
   2. the precise purposes for which the data will be used
   3. that the data will not to be used for any other purpose or passed to anyone else.
   4. that the data will not be linked to other data unless this is specified in the agreement, or is specifically agreed by the Registry at a later time. The National Cancer Registry will have to give consent for the data to be linked with any other databases.
   5. that the data will not be used to contact the patient or family.
   6. that the data must not be used to identify, or attempt to identify, any individual, family or dwelling, or to contact any patient or their family, and may not be published in a way which would allow any individual, family or dwelling to be identified, either directly or by linkage with other data.
   7. That every precaution will be taken to avoid the identification of individuals or institutions in any publication.
   8. That documents based on the data will be shared with the Registry prior to publication. The National Cancer Registry will be sent a final draft of any publication or report based on the data, and will have the right to have any analysis breaching the above conditions removed or modified.
   9. that the data (all paper and electronic copies) will be deleted or destroyed at an agreed date and to inform the Registry that this has been done (a note should be kept of this data at the time of request and a reminder automatically set up).
   10. that users of the data must ensure that, in complying with the above conditions, they also observe the relevant provisions of the Data Protection Acts and the Freedom of Information Act.
   11. that data will not be released to users outside the State without the permission of the Director (or other authorised person). The permission of the Data Protection Commissioner may be required for some transfers, especially outside the EU.

One corollary of the above conditions is that requests which come from outside recognised medical, research or academic institutions, where the above conditions may be difficult to observe, will be treated with particular care.

**National Cancer Registry Ireland**

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| **APPLICATION FOR AN ANONYMISED DATASET, Form DR-1** |

*NOTE: This form is specifically for requests where the data or information is not routinely provided by the Registry (e.g. via website download). More options for your data request are listed below. Before completing this form, please read the following procedures and conditions of use of Cancer Registry data before proceeding. More detailed information on Registry procedures and policy on data provision can be viewed on the Registry’s website (*[*www.ncri.ie*](http://www.ncri.ie)*)*

**Procedures for provision of data by the National Cancer Registry**

The Registry will supply data in response to any reasonable or bona fide request, provided that complying with the request does not conflict with our obligations of confidentiality or with those under the Data Protection Act, 1988 (amended 2003). The use of the data by the applicant must be also consistent with the Data Protection Acts. Data will be anonymised where feasible, and, if not, consent must be obtained.

**The Registry classifies the data held into three categories: confidential, restricted and unrestricted.**

**(1) Confidential data** is any **sensitive personal[[13]](#footnote-13)** information (see section 3.1.2 for definitions) relating to an identified or identifiable[[14]](#footnote-14) person, whether alive or dead. This definition extends to deceased persons many of the protections available under the Data Protection Acts. Data, by which the persons concerned can no longer be reasonably identified, are not considered as personal data.

**Confidential data held by the Registry on living persons will be released only with the written explicit consent of the data subject.** The only exception to this is where the data is requested by a hospital which has a cancer database and has a data processing agreement with the National Cancer Registry. The patient should be aware that their data is stored on such a database and that the hospital may obtain data from the National Cancer Registry. Requests for confidential data must be made by, or on behalf of, the Data Controller (the hospital or HSE CEO) specifying that the data requested is for data quality control or audit purposes only, and a declaration on use must be signed. All requests for confidential information must be approved by the Director. Processing and release of confidential data relating to living persons is subject to the Data Protection Acts. In the case where the Registry is passing data back to a hospital where patients have already been treated, we can pass this data only to somebody acting with the approval of the “data controller” in that hospital (normally the hospital CEO or equivalent).

**(2) Restricted data** is any data, which is not confidential, but the use and dissemination of which is subject to certain restrictions by the Registry. Processing and release of restricted data is not subject to the Data Protection Acts but is governed by the policies of the National Cancer Registry. Any person requesting restricted information must do so in writing, either by post, fax or email[[15]](#footnote-15).

**(3) Unrestricted data** is all information not classified as confidential or restricted and is freely available to any member of the public on request. However, the Registry reserves the right to refuse requests for information, or to charge for the service, if, in the Registry’s view, requests involve disproportionate effort, are not made in good faith, have a malicious intent or are excessive in number. Vague requests, such as “information on breast cancer” cannot be dealt with and will be returned to the requester. If the amount of data analysis involved is extensive and/or the data is requested for commercial purposes, a fee may be payable to cover our costs. We attempt to respond to all requests within two working weeks of receipt and should be able to reply to most within a week.

**This document does not apply to requests for information under the Freedom of Information Acts, which should be made to our Freedom of Information Officer, Ms Geraldine Finn, at 021-4318014 or to** [**g.finn@ncri.ie**](mailto:g.finn@ncri.ie)**.[[16]](#footnote-16)**

**National Cancer Registry Ireland**

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| **APPLICATION FOR AN ANONYMISED DATASET** |

***Please read above procedures and conditions of use of Cancer Registry data before proceeding***

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| **CONTACT DETAILS** | |
| **Requester’s Full Name** |  |
| **Title (Mr/Ms/Dr/Prof/Other)** |  |
| **Job Title** |  |
| **Organisation Name & Sector** (government, private company etc) |  |
| **Address** |  |
| **Telephone/Fax Number** |  |
| **Email** |  |
| **Names of other persons with access to this data** |  |

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| **SPECIFICS OF REQUEST** | |
| **Data requested from NCR previously**  *Date of previous request*  *Is present request related to previous request?*  *(if yes, please provide details below)* | (if yes, please tick)  [Enter date or closest approximate]  (if yes, please tick) |
| **Reasons for current request**  *(brief description)* |  |

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| **SPECIFICS OF REQUEST** | |
| **How will data be used?**  For internal/private use (non-publication) only  *Please provide details*  Will other individuals have access to this data  *If yes, please provide details; including full names, organisation etc.*  For research and future publication of results  *Please provide details, timeline, proposed publication date etc.*  **End date of project**  *Data should be destroyed on or by this date and the Registry notified that this has been carried out* | (if yes, please tick)  (if yes, please tick)  (if yes, please tick)  [Enter research time period and expected end date]  [Enter proposed journal name/location of published work]  [Enter details] |

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| **PARTICULARS OF RESEARCH PROPOSAL: DATA ITEMS & ANALYSIS PLAN** | |
| **[Use this space to provide more information on your request] Please provide a comprehensive description of the data items needed and analysis you intend to do using the NCRI data. This is necessary for the Registry to ascertain what data items you will need for the analysis.**  [Continue on separate page/insert additional line spaces if necessary] | |
| **PARTICULARS OF RESEARCH PROPOSAL: DATA ITEMS & ANALYSIS PLAN continued** | |
| **[Use this space to provide more information on your request] Please provide a comprehensive description of the analysis you intend to do using the NCRI data. This is necessary for the Registry to ascertain what data items you will need for the analysis.**  [Continue on separate page/insert additional line spaces if necessary] | |
| **EXAMPLE OF TREATMENT DATA FORMAT** | |
| **Is treatment information required?**  **Format of treatment data:**   1. summary only (treatment received within 12 months of diagnosis)   tumour-directed surgery (yes/no)  chemotherapy (yes/no)  radiotherapy (yes/no)  hormone therapy (yes/no)   1. more details required | (if yes, please tick)  (if yes, please tick and provide PRECISE details) |

**National Cancer Registry Ireland**

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| **APPLICATION FOR AN ANONYMISED DATASET, Form DR-1 DECLARATION BY REQUESTER** |

I have read and understand the conditions under which this information is being provided by the National Cancer Registry.

I undertake that (unless the National Cancer Registry has been specifically requested and has given permission) the data supplied:

1. will be used only for the purposes specified in “Reasons for data request”,
2. will not be transmitted or made available in any format (other than those set out in “Reasons for data request”) to anyone not named in the Request Form,
3. will not be linked to any data not specified in “Reasons for data request”,
4. will be deleted or destroyed at the “End date of project” specified above. The Registry will be informed that this has been done,
5. will not be used to contact any individual patients or their family members,
6. will not be transmitted outside the Republic of Ireland [if data provided in response to a request from within Ireland],
7. will not be published in a way which could identify, or be used to identify, individuals or institutions,
8. will not be published in any format, prior to confirmation by the National Cancer Registry that the publication meets the criteria above,
9. will be acknowledged as “[based on or derived from] data provided by the National Cancer Registry” (or similar agreed acknowledgement) in any publication (print or online, limited circulation or otherwise.

**Name:**

**Signature: Date:**

1. Although the definition of “confidential” information used here is similar to that given for “sensitive personal” data in the Data Protection Acts, the Registry definition is extended to cover deceased persons, who are not covered by the Acts. [↑](#footnote-ref-1)
2. An *identifiable person* is one who can be identified, directly or indirectly, in particular by reference to an identification number, or to one or more factors specific to his/her physical, physiological, mental, economic, cultural or social identity [↑](#footnote-ref-2)
3. Simple requests, such as the total number of cases of a particular cancer registered in a specified year, may be dealt with over the telephone. [↑](#footnote-ref-3)
4. The Registry’s policies on Freedom of Information are available at <http://www.ncri.ie/about/freedom-information> [↑](#footnote-ref-4)
5. Guide to professional conduct and ethics for registered medical practitioners. Medical Council, 2009. [↑](#footnote-ref-5)
6. Coleman M, Muir CS Menegoz F. Confidentiality in the Cancer Registry. Br J Cancer 1992; **66:** 1138-1149. [↑](#footnote-ref-6)
7. Responsibility in the use of personal medical information for research: Principles and Guide to Practice. Statement by the Medical Research Council. B.M.J. 1985; **290**:1120-1124. [↑](#footnote-ref-7)
8. Gordis L., Gold E. Privacy, Confidentiality and the use of medical records in research. Science 1980**; 207**:153-156. [↑](#footnote-ref-8)
9. Simple requests for aggregate data, such as the total number of cases of a particular cancer registered in a specified year, may be dealt with over the telephone. [↑](#footnote-ref-9)
10. Appropriate Ethics Committees are those (1) which are recognised by the Department of Health and Children under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 or (2) which have been established by an academic, professional or healthcare body and operate in accordance with the procedures set out in “Operational procedures for research ethics committees: guidance 2004” (Irish Council for Bioethics, 2004). [↑](#footnote-ref-10)
11. That is, which form part of a full clinical genetics service provided by a healthcare institution. [↑](#footnote-ref-11)
12. EU Directive 95/46/EC. As implemented by the Data Protection (Amendment) Act 2003. [↑](#footnote-ref-12)
13. Although the definition of “confidential” information used here is similar to that given for “sensitive personal” data in the Data Protection Acts, the Registry definition is extended to cover deceased persons, who are not covered by the Acts. [↑](#footnote-ref-13)
14. An *identifiable person* is one who can be identified, directly or indirectly, in particular by reference to an identification number, or to one or more factors specific to his/her physical, physiological, mental, economic, cultural or social identity [↑](#footnote-ref-14)
15. Simple requests, such as the total number of cases of a particular cancer registered in a specified year, may be dealt with over the telephone. [↑](#footnote-ref-15)
16. The Registry’s policies on Freedom of Information are available at http://www.ncri.ie/ncri/foifiles/Manual.pdf [↑](#footnote-ref-16)