Office for National Statistics

Procedures for the release of cancer microdata

August 2010

Edition No.: **1.0**

Editor: **Emma Gordon**

Office for National Statistics

1.0

A National Statistics publication

National Statistics are produced to high professional standards set out in the Code of Practice for Official Statistics. They are produced free from political influence.

About us

The Office for National Statistics

The Office for National Statistics (ONS) is the executive office of the UK Statistics Authority, a non-ministerial department which reports directly to Parliament. ONS is the UK government's single largest statistical producer. It compiles information about the UK's society and economy, and provides the evidence-base for policy and decision-making, the allocation of resources, and public accountability. The Director-General of ONS reports directly to the National Statistician who is the Authority's Chief Executive and the Head of the Government Statistical Service.

The Government Statistical Service

The Government Statistical Service (GSS) is a network of professional statisticians and their staff operating both within the Office for National Statistics and across more than 30 other government departments and agencies.

Contacts

This publication

For information about the content of this publication, contact
Emma Gordon
Tel: 01633 455 866
Email: Emma.Gordon@ons.gsi.gov.uk

Other customer enquiries

ONS Customer Contact Centre
Tel: 0845 601 3034
International: +44 (0)845 601 3034
Minicom: 01633 815044
Email: info@statistics.gsi.gov.uk
Fax: 01633 652747
Post: Room 1.101, Government Buildings,
Cardiff Road, Newport, South Wales NP10 8XG
www.ons.gov.uk

Media enquiries

Tel: 0845 604 1858
Email: press.office@ons.gsi.gov.uk

Copyright and reproduction

Contents

1. Introduction and background

1.1 Summary

This document discusses the release of cancer data, which may be derived from cancer registration and/or mortality data, and includes details of what data may be released and under what conditions.

The publication of tables based on health-related data should conform to the ONS Review of the Dissemination of Health Statistics: Confidentiality Guidance (Health Review), see:

http://www.statistics.gov.uk/about/data/disclosure/health-statistics.asp

This guidance complies with the UK Statistics Authority Code of Practice for Official Statistics (Code of Practice).

ONS also releases microdata (individual level record data), under certain conditions. Microdata releases must be approved by either:

(i) The ONS Deputy Director for the Centre for Health Analysis and Life Events

- A responsibility currently delegated to the Head of Life Events, where data are released on behalf of the Secretary of State for health (SoS). The purposes and persons considered to come within the remit of the SoS are subject to agreement between ONS and the Department of Health (DH).

(ii) The ONS Microdata Release Panel (MRP)

- When data are released to Approved Researchers for statistical purposes, and the data are deemed disclosive. In case where datasets are deemed non-disclosive by the Statistical Disclosure Control unit (SDC) in ONS, researchers do not need Approved Researcher status to obtain the dataset, and approval is delegated to the Microdata Release Unit (MRU).

In either case, SDC provide advice on whether the data to be released are disclosive, and, if required, how to make the data non-disclosive. No requests are classified as non-disclosive by either route without a risk assessment first being carried out by SDC. See Annex A for further details of the risk assessment process.

All microdata releases must be accompanied by an appropriate Data Access Agreement (DAA), which is signed by both the recipient(s) and the Responsible Statistician in ONS. The DAA includes clauses on the following issues:

- Unauthorised linking of the data with other data is forbidden
- Publishing individual-level data or sharing this with a third party is forbidden
- All published tables or datasets shared with a third party must be appropriately disclosure controlled (see link to the ‘Health Review’ above for guidance)
- Data must be kept securely and destroyed at the end of the agreed period.

1.2 Definitions used in this document

“Non-disclosive data”: a dataset from which an individual could not be identified, as assessed by SDC. If data are at individual-level, then even if it has been assessed as non-disclosive, ONS would not want this data to be released into the public domain in this form. Researchers are therefore required to sign a non-disclosive DAA to obtain this type of data (see Annex B).

“Disclosive data”: a dataset from which it would be possible to gain more information about an individual, but which does not contain any personal identifiers, as assessed by SDC. Researchers are required to sign a disclosive DAA to obtain this type of data (see Annex C and D for examples of SoS and MRP disclosive DAAs respectively).

“Identified data”: a dataset that contains personally identifiable variables that either directly identifies an individual (eg: name), or indirectly, via linkage to another data source (eg: NHS number). Researchers are required to sign a disclosive DAA to obtain this type of data (see Annex C and D for examples of MRP and SoS disclosive DAAs respectively), and have either:

- Research Ethics Committee (REC) approval and section 251 support, if carrying out medical research
- Section 251 support, if not carrying out medical research
- Patient consent and REC approval.

2. Legal basis

2.1 Legal basis for ONS to process cancer microdata

The Health Service (Control of Patient Information) Regulations 2002 Statutory Instrument No. 1438, Regulation 2, permits confidential patient information relating to patients referred for the diagnosis or treatment of cancer to be processed for the following purposes:

> *(a) the surveillance and analysis of health and disease;*
>
> *(b) the monitoring and audit of health and health related care provision and outcomes where such provision has been made;*
>
> *(c) the planning and administration of the provision made for health and health related care;*
>
> *(d) medical research approved by research ethics committees;*
>
> *(e) the provision of information about individuals who have suffered from a particular disease or condition where –*
>
> > *(i) that information supports an analysis of the risk of developing that disease or condition; and*
> >
> > *(ii) it is required for the counselling and support of a person who is concerned about the risk of developing that disease or condition.*

This regulation was made under Section 60 of the Health and Social Care Act 2001 and continues to have effect under Section 251 of the NHS Act 2006.

The processing of confidential patient information for these purposes may be undertaken by organisations approved by the Secretary of State. Authority under the NHS Act is given to ONS by the SoS via a Service Level Agreement (SLA) between DH and ONS. The wording of the current SLA that describes the services DH expect ONS to carry out as part of this SLA are as follows:

SERVICE PROVIDED

The Office for National Statistics (ONS) will provide and analyse national statistics on cancer registrations submitted by the regional cancer registries in England and Wales and on cancer mortality, to enable the Department of Health (DH), the NHS and others to monitor changing levels and patterns of the disease.

Processing of information

1. ONS will compile a register of cases of cancer in England and Wales to quality standards agreed with the Department of Health. It is expected that around 380,000 new registrations, 280,000 associated corrections by registries, and 33,000 deletions will be processed each year.

2. ONS will process and store the data in accordance with the requirements of;

- *the Data Protection Act 1998;*
- *the Code of Practice for Official Statistics ;*
- *the IACR/IARC Guidelines on Confidentiality in Cancer Registries (published in the British Journal of Cancer 1992, 66, 1138-1149);*
- *the ENCR Guidelines on Confidentiality (2002);*
- *the UKACR Guidelines on Confidentiality.*
- *The NHS Act 2006; and*
- *The Statistics and Registration Service Act 2007.*

AD-HOC QUERIES

3. The Department of Health gives approval for ONS to make available to bona fide researchers, other Government Departments, cancer charities and members of the public, both individual and aggregated cancer registration data, subject to confidentiality constraints.

An organisation that processes confidential patient information under Statutory Instrument 2002, No. 1438, Regulation 2 is required to inform the Patient Information Advisory Group (PIAG) of that processing, and to make available to the Secretary of State information to assist in the investigation and audit of that processing, as required by section 60(4) of the Act.

The functions of the Patient Information Advisory Group (PIAG), have now been taken over by the Ethics and Confidentiality Committee (ECC) of the National Information Governance Board (NIGB).

2.2 Legal basis for ONS to release cancer microdata

Data derived from cancer registration are held by ONS on behalf of the SoS, and their release for research and related purposes is authorised by SoS under the NHS Acts, through a SLA between DH and ONS, and with the permission of NIGB.

Data derived from death registration are held by ONS in its own right, and their release is governed by the Statistics & Registration Service Act (SRSA), 2007.

A release of data combining both cancer and death registrations, for example cancer registration records with the addition of date of death, must comply with the requirements of both the SRSA and the NHS Acts, and the procedures laid down pursuant to both.

2.2.1 Releasing non-disclosive datasets

If SDC carry out a risk assessment on a dataset and classify it as non-disclosive, because it contains no information from which an individual could be identified, then non-disclosive data can be supplied in accordance with powers in the Statistics and Registration Service Act 2007, section 39(10):

39 Confidentiality of personal information

(1) Subject to this section, personal information held by the Board in relation to the exercise of any of its functions must not be disclosed by—

> *(a) any member or employee of the Board,*
>
> *(b) a member of any committee of the Board, or*
>
> *(c) any other person who has received it directly or indirectly from the Board.*

(2) In this Part "personal information" means information which relates to and identifies a particular person (including a body corporate); but it does not include information about the internal administrative arrangements of the Board (whether relating to its members, employees or other persons).

(3) For the purposes of subsection (2) information identifies a particular person if the identity of that person—

> *(a) is specified in the information,*
>
> *(b) can be deduced from the information, or*
>
> *(c) can be deduced from the information taken together with any other published information.*

(9) A person who contravenes subsection (1) is guilty of an offence and liable—

(a) on conviction on indictment, to imprisonment for a term not exceeding two years, or to a fine, or both;

(b) on summary conviction, to imprisonment for a term not exceeding twelve months, or to a fine not exceeding the statutory maximum, or both.

(10) Subsection (9) does not apply where the individual making the disclosure reasonably believes—

(a) in the case of information which is personal information by virtue of subsection (3)(a), that the identity of the person to whom it relates is not specified in the information,

(b) in the case of information which is personal information by virtue of subsection (3)(b), that the identity of that person cannot be deduced from the information, or

(c) in the case of information which is personal information by virtue of subsection (3)(c), that the identity of that person cannot be deduced from the information taken together with any other published information.

If data are at individual-level, then even if it has been assessed as non-disclosive we would not want this data to be released into the public domain in this form, and so researchers are required to sign a non-disclosive DAA to obtain this type of data (see Annex B).

2.2.2 Releasing disclosive data to support the work of the Secretary of State

If the researchers making the data request are carrying out their study on behalf of the Secretary of State, then the Head of Life Events at ONS will assess their application for individual-level data, on the condition that documentary evidence is provided to this effect (eg: a funding letter), and if:

(a) The data contain no “identified data” (personally identifiable variables) and NIGB have notified ONS that they are content for the data to be released under these conditions, or

(b) The researchers have REC approval and section 251 support for their study, if carrying out medical research

(c) The customers have section 251 support for their study, if not carrying out medical research, or

(d) The researchers have patient consent and REC approval for their study

- data are released under the NHS Act 2006, and Section 42 of the SRSA (2007), the wording of which is as follows:

42 Information relating to births and deaths etc

(1) The Registrar General for England and Wales may, for the purpose of the exercise by the Board of any function, disclose to the Board any information to which this section applies.

(2) This section applies to—

(a) any information entered in any register kept under the Births and Deaths Registration Act 1953 (c. 20);

(b) any other information received by the Registrar General in relation to any birth or death;

(c) any information entered in the Adopted Children Register maintained by the Registrar General under section 77 of the Adoption and Children Act 2002 (c. 38);

(d) any information entered in any marriage register book kept under Part 4 of the Marriage Act 1949 (c. 76);

(e) any information relating to a civil partnership which is recorded under the Civil Partnership Act 2004 (c. 33) at the time of the formation of the civil partnership.

(3) In subsection (2)(b) "birth" has the same meaning as in the Births and Deaths Registration Act 1953.

(4) The Board may, for the purpose of assisting the Secretary of State or the Welsh Ministers in the performance of his or their functions in relation to the health service, disclose to him or them any information referred to in subsection (2)(a) to (c) which is received by the Board under this section.

See Annex C for an example of a SoS DAA for disclosive data.

2.2.3 Releasing disclosive data to Approved Researchers

If the researchers making the data request are not carrying out their study on behalf of the Secretary of State, they must first be authorised by ONS as an Approved Researcher for their study. Details of the Approved Researcher application process can be found here:

http://www.statistics.gov.uk/CCI/nugget.asp?ID=1872&Pos=&ColRank=2&Rank=448

If a person is passed as an Approved Researcher for a particular study, the Microdata Release Panel will assess their application for individual-level data. If this Panel deems the research purpose to be in the public interest, and:

(a) The data contain no "identified data" (personally identifiable variables) and NIGB have notified ONS that they are content for the data to be released under these conditions, or

(b) The researchers have REC approval and section 251 support for their study, if the study is medical research

(c) The researchers have section 251 support for their study, if the study is not medical research

(d) The researchers have patient consent and REC approval for their study

- the application will be passed and a DAA worded to the effect that the data are released under Section 251 of the NHS Act 2006, and Section 39(4,i) of the Statistics & Registration Service Act, the wording of which is as follows:

39 Confidentiality of personal information

(1) Subject to this section, personal information held by the Board in relation to the exercise of any of its functions must not be disclosed by—

(a) any member or employee of the Board,

(b) a member of any committee of the Board, or

(c) any other person who has received it directly or indirectly from the Board.

(4) Subsection (1) does not apply to a disclosure which—

(i) is made to an approved researcher.

See Annex D for an example of an MRP (Approved Researcher) DAA for disclosive data.

2.3 Summary of the ONS position on release of microdata

Release of personal information held by ONS, other than by one of the legal exemptions above, is a criminal act. The Code of Practice states that all relevant data sources must be taken into account when protecting the identification of an individual. This implies that the existence of private data sources must be borne in mind when releasing microdata. For this reason, ONS policy is that microdata that are not identifiable are not necessarily publishable (see Annex A for details of the risk assessment process). The use of private data sources to identify an individual are prevented by the use of DAAs (see Annexes B, C and D).

3. Process of data release

3.1 Non-identifiable data releases of cancer registration / mortality data

A release of data combining both cancer and death registrations, for example cancer registration records with the addition of date of death, must comply with the requirements of both the SRSA and the NHS Acts, and the procedures laid down pursuant to both.

Since ONS are experienced in dealing with confidential data of many different forms (births, deaths, cancer registration, social and business survey, for example), we reserve the right to make decisions about when a data request contains disclosive data, and when it does not. In making these decisions, we are guided by the rules and principles as set out in the legislation and codes of practices listed above.

If a researcher requested a dataset that SDC decided was also non-disclosive (see Annex A), then we would approve the release under these conditions after a non-disclosive DAA has been signed (see Annex B). For this type of data release, an SDC risk assessment confirming the non-disclosive status of the data requested is always required.

The Microdata Release Unit and the team dealing with Secretary of State applications can request a Risk Assessment be carried out by SDC for any data request.

3.2 Disclosive releases of data

3.2.1 Cancer registration / mortality data, with no personal identifiers

ONS does not consider dates such as date of birth and date of death (both of which are variables derived from information recorded at death registration) to be personal identifiers in their own right, since they do not uniquely identify an individual in a population. However, if a researcher requested a dataset that SDC deemed disclosive (for example, a dataset that included date of birth, date of death and health data such as date of cancer registration), ONS would seek clarification from NIGB on whether the ECC would consider such a request to contain identifiable data. For the purposes of section 251 of the NHS Act, (2006), this particular example of combined death registration and cancer registration data would be deemed identifiable by the ECC. Therefore, the researchers requesting such a dataset would need to apply for (and be granted) section 251 support from NIGB before ONS could release the data, either via the SoS or MRP route. If the researchers were carrying out a medical research study, they would also need REC approval.

To summarise, if NIGB deemed a dataset to contain identifiable data, even if no explicitly personally identifiable variables had been requested, ONS would not proceed with the request until the researcher had REC approval and section 251 support if carrying out medical research, or section 251 support if not carrying out medical research (see section 3.2.3), or patient consent and REC approval (see section 3.2.4). If NIGB decided section 251 support was not required, we would request written evidence of this decision and then process the request as a disclosive request (see sections 3.2 and 3.3 for legal basis, and Annexes C and D for example of disclosive SoS and MRP DAAs respectively).

3.2.2 Release of ‘mortality only’ cancer microdata, with no health-related personal identifiers

Data derived from death registration are held by ONS in its own right, and their release is governed by the SRSA, 2007.

If a researcher requested a dataset that was deemed disclosive by the ONS Statistical Disclosure Control (SDC) group (see Annex A), then we would approve the release, under one of the following provisions:

a) They were passed as Approved Researchers by ONS for the purpose of this study, their data request was passed by the Microdata Release Panel, and they had signed an appropriate MRP Data Access Agreement (DAA)

b) They were carrying out their work on behalf of the Secretary of State, and had evidence to this effect (eg: funding letter from DH) , and they had signed a Secretary of State DAA

3.2.3 Release of 'mortality only' cancer microdata, with health-related personal identifiers

If a researcher requested a dataset that contained variables derived from death registration and a health-related personal identifier (for example, NHS number), then the request would not be processed unless the researchers had:

(a) REC approval and section 251 support for their study if carrying out medical research, or

(b) Section 251 support for their study if not carrying out medical research, or

(c) Patient consent and REC approval. See section 3.2.4 below for further information on what evidence is required to determine whether appropriate consent has been requested / granted.

If either of the above conditions were met, then ONS would approve the release under one of the following provisions:

a) They were passed as Approved Researchers by ONS for the purpose of this study, their data request was passed by the Microdata Release Panel, and they had signed an appropriate MRP Data Access Agreement (DAA)

b) They were carrying out their work on behalf of the Secretary of State, and had evidence to this effect (eg: funding letter from DH) , and they had signed a Secretary of State DAA

The MRP and the team dealing with SoS applications can request a Risk Assessment be carried out by SDC for any data request, and would do so if in any doubt about whether a dataset contained any health-related personally identifiable variable(s).

3.2.4 Releases of identifiable cancer registration / mortality data, with patient consent

If a researcher requested a dataset that was limited to a cohort of people that had given their consent to be in the study, then we would approve the release, pending receipt of documentary evidence to this effect and evidence of REC approval for the study, under one of the following provisions:

a) Their data request was passed by the Microdata Release Panel, and they had signed an appropriate MRP Data Access Agreement (DAA)

b) They are carrying out their work on behalf of the Secretary of State, and have evidence to this effect (eg: funding letter from DH), and they had signed a Secretary of State DAA

To enable an assessment of whether appropriate patient consent was requested, researchers are required to provide copies of patient consent forms to ONS. Wording such as 'I understand that information held by the NHS and records maintained by the General Register Office may be used to keep in touch with me and follow up my health status' would be deemed appropriate. This is not prescriptive but exact wording used in consent forms should have broadly the same meaning. We also assess the text of patient information leaflets used within research studies, to check no inappropriate guarantees have been given; for example, a statement saying ‘no personal data will be shared with a third party’.

If ONS was in any doubt about the nature of the consent been given, or if there were any concerns that the consent was potentially invalid for any reason, we would seek the advice from the NIGB Secretariat before proceeding with the request.

3.2.5 Releases of identifiable cancer registration / mortality data, without patient consent

Researchers / customers are required to provide written evidence of:

(a) REC approval and section 251 support for their study if carrying out medical research, or

(b) Section 251 support for their study if not carrying out medical research

- where they are requesting cancer registration data that explicitly includes patient identifiable data, defined as that which allows identification of an individual from the data, or from the data taken together with other published information (for example, names, addresses, NHS numbers).

No person or organisation carrying out work on behalf of the Secretary of State, or as an Approved Researcher, is given access to patient identifiable data (eg: names, addresses, NHS numbers) without first meeting the appropriate set of conditions (as described above) first. Each year ONS provide NIGB with a complete list of all patient identifiable cancer microdata releases that have been approved and released.

Annex A: Risk assessment

The process of risk assessment carried out by the ONS SDC unit is based on:

1. The nature of the data
2. Possible intruder scenarios
3. Key variables

1. The nature of the data

Cancer microdata that are requested for research are derived from Cancer Registration data, and also from Mortality data where the cause of death, or underlying cause of death, is cancer. The variables in the records are of two kinds: demographic and health-related.

1.1 Demographic variables

The demographic variables generally requested are some or all of the following:

- age or age-group
- place of residence, i.e. Government Office Region (GOR)
- sex [1]
- age at death
- date of death
- ethnicity

1.2 Health-related variables

The health-related variables generally requested are some or all of the following:

- date of cancer registration
- age at cancer registration
- diagnosis, i.e. ICD code
- histology
- outcome, i.e. whether died

[1] ONS require cancer registries to register patients with their sex at birth as this aids matching and checking processes and sex-specific cancers must be reported with a medically valid sex

2. Possible intruder scenarios

When assessing the disclosure risk of microdata, it is necessary to first consider the intruder scenarios. These are assumptions about what an intruder might know about individuals to whom the data refer, and what information will be available to match against the microdata and potentially make an identification. The consideration of scenarios indicates some of the variables which are likely to be used by an intruder. When releasing Cancer microdata, there are two scenarios which need to be considered: use of published datasets and spontaneous recognition.

2.1 Scenario 1 – use of published datasets

The published data which are relevant to this scenario include:

(i) Cancer registration statistics – 3-digit ICD-10 code by sex by age-group (5 year age bands).

(ii) Cancer registration statistics – 3-digit ICD-10 code by sex by Government Office Region (GOR).

(iii) Mortality statistics, underlying cause cancer – 4-digit ICD-10 code by sex by age-group (5 year bands).

There is also a CD-ROM containing microdata on Cancer incidence for 1971 onwards, which is available under licence.[2] The records in these data contain the following variables:

- sex
- age at diagnosis (single year and 5 year age-groups)
- year of diagnosis
- full ICD code
- histology, coded
- behaviour, coded

These data were assessed as being not personal information, but not publishable. The licence for this CD-ROM prohibits both linking the data with any others and attempting to identify any individual from the data. It also refers to the Health Review as guidance on what statistics may be published from these data. Therefore this CD-ROM is not considered to be in the public domain .

Basic mortality data, including cause of death, date and age at death are considered to be in the public domain. Therefore the detail of some of the health related variables needs to be reduced to manage the risk of disclosure. Thus, for example, for a dataset to be assessed as non-disclosive, date of death would ONLY be given as year of death.

[2] From 2008. Prior to this time, this CD-ROM dataset was considered to be in the public domain, as it was available on request, as it had been classified as non-disclosive. All requests for the dataset from 2008 onwards have only been processed via licence (a signed non-disclosive DAA).

There are datasets in the public domain which contain demographic variables, examples are the Electoral Register and commercial datasets, such as consumer profile databases. A typical commercially available dataset may include the following variables:

- Name
- Address and Postcode
- Age
- Sex
- Ethnicity
- Number of cars
- Number of children, given in 5 year age-groups (e.g. 1 child aged 0-4, 2 children aged 5-9)
- Size of household
- Tenure, House type and Number of rooms
- Occupation (high-level)
- Income (banded)
- Qualifications

Of these, only sex, ethnicity and address are relevant to Cancer microdata. An intruder could match these public datasets with the Cancer microdata on the key demographic variables and potentially identify an individual. Therefore, these demographic details need to be restricted in order to make it sufficiently difficult for an intruder to do this with any degree of certainty. Thus, for example we recommend that address is only given as GOR, which gives a sufficient level of uncertainty to any possible identification of an individual which may be made by use of such data.

2.2 Scenario 2 – spontaneous recognition

An intruder may recognise an individual in Cancer microdata, for example because of the rarity of a particular type of disease. However, in this case the DAA would prevent him or her from making the identification public.

3. Key variables

Although the intruder scenarios indicate that the risk of identifying an individual in Cancer microdata is low, we should consider the key variables which are generally requested with such data. These are listed in section 1 above. The following tables provide guidance as to what level of detail may be given for these variables, if the data are to be assessed as non-disclosive.

3.1 Guidance on preparing non-disclosive Cancer microdata

The following tables are provided for guidance only. They include all the variables which are most commonly requested in Cancer microdata. However each dataset needs to be assessed individually to ensure that it is non-disclosive. The requirements of the user should always be borne in mind; if one variable is required at a more detailed level, then another one should be

provided at less detail. For example, if ethnicity is required at 16-category level, then age could be banded, or geography could be “England & Wales” only.

Demographic variables

Variable	Level of detail
Place of residence	Nothing lower than GOR
Sex	Male/female
Ethnicity	Grouped into 6 categories
Date of death	Year only
Age at death	In years

Health-related variables

Variable	Level of detail
Date of Cancer registration	Year only
Diagnosis	ICD-10 code to 4 digits (or ICD-9 code for historical data)
Age at Cancer registration	In years
Histology	Coded only, i.e. not free text
Outcome	Died = yes/no

4. Summary

Cancer microdata are a valuable resource for research. If the guidance above is followed, the microdata will generally be assessed as non-disclosive, or not personally identifiable information, and may be released to a researcher as such. Each dataset must be assessed individually by the SDC team, who use a combination of statistical skills, data knowledge and experience. A data access agreement must always be signed.

Annex B: Example Data Access Agreement, when data are being supplied in non-disclosive form in accordance with its powers in the Statistics and Registration Service Act 2007.

For use when an individual-level dataset has been assessed by SDC as non-disclosive

Data Access Agreement – MRP No. xxx/xxxx

DATA ACCESS AGREEMENT for Non-disclosive data

Agreement between the Office for National Statistics and ……..

1. Data required

2. Name of the main statistical contact

3. Purpose for which the data are provided

4. Products and publications

4.1. The outputs arising from the use of these data include ……

4.2. All outputs resulting from access to these data must meet the guarantee contained in the Code of Practice for Official Statistics.

5. Matching or linking

No unspecified or unauthorised matching of the data will take place.

6. Lawful use of the data

6.1. Data will be processed in accordance with the Data Protection Act (1998).

6.2. Access to these data will not breach any commitments made to respondents to protect the confidentiality of the data provided.

6.3. These records were processed by the ONS under s.251 of the NHS Act 2006[3] and are being supplied in non-disclosive form in accordance with its powers in the Statistics and Registration Service Act 2007.

6.4. These data may not be published nor may they be passed to a third party, without the specific agreement of ONS.

6.5. The information will only be used for valid statistical research purposes and its use will meet the criteria and principles established in the Code of Practice for Official Statistics.

[3] Statement included only if cancer registration data for part of the data request. If data are derived solely from mortality registrations, this is omitted.

7. Time limits

7.1. The data will be provided for the period ……. to …….

7.2. Any requests for extension to the access period must be referred to ONS for approval.

8. Review *

Where the data are provided under a long-standing or permanent arrangement, a review of the access arrangements is to be conducted, within a period not exceeding five years. Arrangements for the review will be communicated to the beneficiary of access by ONS in due course.

9. Arrangements when period of access expires

9.1 The beneficiary will ensure that the data are destroyed to the standards that meet government standards for secure and complete destruction.

OR

The beneficiary will return the data to the ONS

9.2 The beneficiary agrees to destroy all copies of the data, including temporary copies, CDs, printed copies, personal copies, back-ups, derived datasets and all electronic copies.

10. Security of the data

10.1 Registration/Notification number registered with the Data Protection Act: Z********

10.2 The physical and technical security of the data will be maintained at all times, and for health data, in accordance with the NHS Information Security Code of Practice.

10.3 Data will not be accessed at a private residence, or via any portable device.[4]

11. Breach and Dispute Procedures.

Any disputes arising between the providing and beneficiary will be resolved initially between the principals to the agreement. Otherwise, outstanding issues will be referred to the National Statistician.

12. Approval

The signatories believe this agreement is compliant with the statements of principle in the Code of Practice for Official Statistics. Where this agreement may appear to contradict the statements of principle in the Code, the Code takes precedence, unless explicitly stated.

12.1 Beneficiary…….

[4] Any remote access system would need to be approved by IM security.

The Beneficiary / Responsible Statistician / Representative for the beneficiary organisation approves the terms of this Agreement and agrees to meet the requirements specified.

Name…… Signature: ……..

Status in the organisation:

Date:

12.2 ONS Approval

The Responsible Statistician for the Office for National Statistics authorises the provision of access to the data to the beneficiary organisation under the terms specified in this Agreement

Name……..Signature: ……..

Status in the organisation:

Date:

PLEASE RETURN TO: EMMA GORDON, ONS, GOVERNMENT BUILDINGS CARDIFF ROAD NEWPORT NP10 8XG

Annex C: Example Data Access Agreement, where data are released under S251 of the NHS Act (2006) and S 42(4) of the SRSA Act (2007)

For use when requestor has provided written evidence that the work is being carried out on behalf of the Secretary of State for Health.

[NAME OF ORGANISATION TO WHICH DATA ARE TO BE RELEASED]

DATA ACCESS AGREEMENT

Agreement for the supply of cancer registration data for England to [NAME OF ORGANISATION]

1. Data required

[One line description of dataset requested] (full details of all data request specified in Annex A for list of data items).

2. Access Period

The period of access for this dataset is for 1 year. Future updates will be covered by separate Data Access Agreements as these data become available.

3. Purpose for which the data are provided

[Detailed description of purpose]

If during the year additional uses of the data are identified, these should be notified to ONS and the approval of data owners obtained.

4. Products and publications

4.1. No contact will be made with any individual identified in the information supplied without the prior approval of ONS.

4.2. The information will not be released to any other individual(s) or organisation(s) not directly connected with the work specified in section 3 without the prior approval of ONS, except in the form of non-disclosive statistical tables or conclusions.

4.3. All outputs resulting from access to these data must meet the guarantee contained in the Briefing Note: ONS policy on protecting confidentiality within birth and death statistics and the Code of Practice for Official Statistics.

5. Minimum information needed

The level of data required is proportionate to the stated purpose(s). All the data provided are required to achieve the purpose(s) specified in section 3.

6. Matching or linking

Linkage of the information supplied to any other non-NHS information relating to identifiable individuals will only be attempted for the purpose(s) specified in section 3 and with the prior agreement of data owners.

7. Duplication

Any intended duplication of the data will only be for the purpose(s) specified in section 3. No other unspecified and unauthorised duplication of the microdata may take place.

8. Lawful use of the data

8.1. Data will be processed in accordance with the Data Protection Act (1998).

8.2. Access to these data will not breach any commitments made to respondents to protect the confidentiality of the data provided.

8.3 These data are released in accordance with the provisions of the National Health Service Act 2006 (section 251 and 270) and the Statistics and Registration Service Act 2007 (section 42.4).

NIGB have advised that the approval for the processing of patient identifiable information under section 251 of the NHS Act 2006 (PIAG [ref no]) is still valid (checked [date]). [This section only included if the data request includes name, address or NHS number at present]

8.4. The information will only be used for the purpose(s) specified in section 3 and its use will meet the criteria and principles established in the Briefing Note: ONS policy on protecting confidentiality within birth and death statistics and the Code of Practice for Official Statistics.

9. Security of the data

9.1. Data Protection Act registration number of organization [number].

9.2. The Responsible Statistician / Representative of the named cancer registries will ensure that their staff, including any contractors, know, understand and guarantee to maintain the confidentiality requirements of each of their statistical resources and will ensure that anyone involved with the processing of the statistical resource is aware of the penalties of wrongful disclosure.

9.3. The physical and technical security of the data will be maintained at all times, and for health data, in accordance with the NHS Information Security Code of Practice. No disclosive information will be sent by fax or email (unless via GSI for a GSS customer) and, if posted, will be encrypted to approved standards[5] (PGP or Private Crypto – not zipped) to protect the data and despatched by Royal Mail Special Delivery service or by courier.

9.4. Hard copies of the data will be stored securely in a locked filing cabinet. Access to the microdata will be restricted to those named on the Data Access Agreement who guarantee to

[5] The standard for NHS generated data is AES 256 bit encryption.

protect and safeguard the confidentiality of the data at all times. Access to data will be via restricted-access password protection.

9.5. The beneficiaries of the data will ensure that access to the data, any copies made of the data and the information contained in them is limited solely to the person(s) who have signed this Agreement. All other individual(s) who will have access to the data must sign the short declaration of use.

9.6. The confidentiality of the data will be preserved in outputs and publications, as detailed in section 4.

9.7. The means of access to the data (such as passwords or pass-phrases) are to be kept secure and only disclosed by the Beneficiary to those individuals who have signed short declarations of use.

9.8. Microdata is to be stored on a secure network, with restricted access and no internet links, or on a stand-alone PC. The PC is to be password protected at boot-up.

9.9. Data will not be accessed at a private residence nor via a laptop or other portable device.[6]

9.10. ONS reserves the right to conduct an on-site audit of the beneficiary's confidentiality and security procedures and practices for guaranteeing the security and confidentiality of the data covered by this agreement, or to require the report of such an audit.

9.10.1. For the purpose of conducting an audit, ONS reserves the right of entry to the premises where the data are stored and processed.

9.10.2. ONS may require the beneficiary to provide copies of any audits of these arrangements, conducted during the period of the agreement, including any audit implementation plans.

9.10.3. Where the data are to be destroyed at the end of the access period, ONS further reserves the right to attend or audit the destruction of the data. All Departments must:

- Destroy paper records containing protected personal data by incineration, pulping or shredding so that reconstruction is unlikely; and
- Dispose of electronic media that have been used for protected personal data through secure destruction, overwriting, erasure or degaussing.

10. Breach and Dispute Procedures.

10.1. The Statistics and Registration Service Act 2007 requires that personal information must not be disclosed by any ‘person who has received the personal information directly or indirectly’ from the ONS, unless directly authorised by the ONS. Disclosures of information that contravene section 39 of the Act will be an offence and may carry penalties, as specified in section 39(9).

10.2. The beneficiary agrees to report immediately to ONS instances of breach of any of the terms of this agreement

[6] Any remote access system would need to be approved by IM security.

10.3. Any disputes arising between the providing and beneficiary organisations will be resolved initially between the principals to the agreement. Otherwise, outstanding issues will be referred to the National Statistician.

11. Approval

The signatories believe this agreement is compliant with the statements of principle in the National Statistics Code of Practice (the Code) and the specific requirements of the Protocol for Data Access and Confidentiality (PDAC). Where this agreement may appear to contradict the statements of principle in the Code or the specific requirements of the PDAC, the Code and the PDAC take precedence, unless explicitly stated.

11.1. Beneficiary Organisation [name]

The Responsible Statistician/ Representative for the named Cancer Registries approves the terms of this Agreement and agrees to meet the requirements specified.

Name……..Signature: ……..

Status in the organisation:

Date:

Name……..Signature: ……..

Status in the organisation:

Date:

11.2. ONS Approval

The Responsible Data Custodian for the Office for National Statistics authorises the provision of access to the data to the beneficiary organisation under the terms specified in this Agreement

Name…….. Signature: ……..

Status in the organisation: .....

Date: .....

PLEASE RETURN TO: EMMA GORDON, ONS, GOVERNMENT BUILDINGS CARDIFF ROAD NEWPORT NP10 8XG

Annex C: Cont.

[Name of organisation]

SHORT DECLARATION LIST

[Description of dataset to be released]

Below are the names of individuals who have access to the records supplied in the ONS cancer registration dataset [description]. Signed short declarations of use are appended.

……
……
……
……
……
……
……
……
……
……
……
……
……
……

Annex C: Cont.

[Name of organization]

SHORT DECLARATION OF USE

ONS Cancer registration data [description of dataset]

I have read the conditions under which the records supplied in the ONS cancer registration dataset [description of data] are supplied by ONS to [name of organisation]. (The conditions are part of the main Data Access Agreement.) I understand that my use of the data must be consistent with the conditions of supply. I will inform the person responsible of any actions that risk breaching their compliance with the conditions.

To Note: This data is now covered by the Statistics and Registration Service Act 2007 that requires that personal information must not be disclosed by any 'person who has received the personal information directly or indirectly' from the ONS, unless directly authorised by the ONS. Disclosures of information that contravene section 39 of the Act will be an offence and may carry penalties, as specified in section 39(9).

Organisation Name ……..……..……

Position in Organisation .....……..……..…..

Organisation Address .....

.....

.....

Postcode ..... Telephone number .....

Email address .....

Name (print) ……..…….....

Signed …… Date……..……..……..

Annex D: Example Data Access Agreement, where data are released under S251 of the NHS Act (2006) and S 39(4) of the SRSA

For use when researcher has been granted Approved Researcher status for a study, and the Microdata Release Panel has approved the study purpose.

Data Access Agreement – MRP No. xxx/xxxx

* Clauses marked with asterisk to be used when appropriate

DATA ACCESS AGREEMENT for disclosive data

Agreement between the Office for National Statistics and ……..

1. Data required

2. Name of the main statistical contact

3. Individual(s) who will have access to the data. (If different to 2. Include details of any contractor who will access the data)

3.1. The person/s who will be supervising the use of the data *

3.2. The person/s who will be carrying out the statistical research *

3.3. Any other individuals *

4. Purpose for which the data are provided

5. Products and publications

5.1. The outputs arising from the use of these data include ……

5.2. These microdata may allow for individuals to be identified. Therefore, the beneficiary will guarantee that no outputs are produced that are likely to identify an individual, unless specifically agreed with them.

5.3. [Insert disclosure rules to be followed here]

5.4. …… have agreed that all releases of data must be approved by ONS *

5.5. All outputs resulting from access to these data must meet the guarantee contained in the Principles of the National Statistics Code of Practice and the Protocol on Data Access and Confidentiality

5.6. ……to provide ONS with details or a copy of any publication, journal or articles, or the dissemination of any output arising from the use of ONS microdata.

5.7. To acknowledge in any publication, whether printed, electronic or broadcast, based wholly or in part on such materials, ONS as the provider of the materials. To declare in any such work that those who carried out the original collection and analysis of the data bear no responsibility for their further analysis or interpretation.

6. Minimum information needed

The level of data required is proportionate to the stated statistical purpose. All the data provided are required to achieve the purpose specified in section 4.

7. Matching or linking

No unspecified or unauthorised matching will take place.

8. Duplication

Any intended duplication of the data will only be for the purpose of making personal copies to aid own research and analysis. No other unspecified and unauthorised duplication of the microdata may take place.

9. Lawful use of the data

9.1. Data will be processed in accordance with the Data Protection Act (1998).

9.2. Access to these data will not breach any commitments made to respondents to protect the confidentiality of the data provided

9.3. This data will be held by you on behalf of the United Kingdom Statistics Authority and are classified as ‘personal information’ according to the Statistics and Registration Service Act 2007.

9.4. The 2007 Act requires that you must not disclose the personal information that you hold on behalf of the Statistics Authority unless directly authorised by the National Statistician. Disclosure without this authority is a criminal offence.

9.5. These data are released in accordance with ……. (insert legislation) *

9.6. The information will only be used for valid statistical research purposes and its use will meet the criteria and principles established in the National Statistics Code of Practice and the Protocol on Data Access and Confidentiality.

9.7. The principles of the Freedom of Information Act apply and nothing provided in this Agreement is confidential to the beneficiary or to ONS.

10. Time limits

10.1. The data will be provided for the period ……. to …….

10.2. Any requests for extension to the access period must be referred to ONS for approval.

11. Review *

Where the data are provided under a long-standing or permanent arrangement, a review of the access arrangements is to be conducted, within a period not exceeding five years. Arrangements for the review will be communicated to the beneficiary of access by ONS in due course.

12. Expiry of the period of access

12.1 At the end of the access period, the beneficiary will return the data to the ONS in the format in which it was originally provided. The data will be encrypted to approved standards (PGP or private crypto – not zipped) and returned by Royal Mail Special Delivery, or by courier

OR

The beneficiary will ensure that the data are destroyed to the standards that meet government standards for secure and complete destruction. *

12.2 The beneficiary agrees to destroy all copies of the data, including temporary copies, CDs, printed copies, personal copies, back-ups, derived datasets and all electronic copies. *

12.3 After expiry of this agreement, the beneficiary will confirm that the original data and all copies of the data have been destroyed and to the required standards

OR

that the data have been returned to the ONS and all copies have been destroyed *

OR instead of 12.1, 12.2 and 12.3 (return or destruction),

12.4 Where the beneficiary wishes to retain the data at the end of the period of access, a review of the access arrangements to be conducted. Subject to satisfactory review, the data may be retained and a new access period agreed *

13. Security of the data

13.1 Registration/Notification number registered with the Data Protection Act: Z********

13.2 The Responsible Statistician will ensure that their staff, including any contractors, know, understand and guarantee to maintain the confidentiality requirements of each of their statistical resources and will ensure that anyone involved with the processing of the statistical resource is aware of the penalties of wrongful disclosure

13.3 The physical and technical security of the data will be maintained at all times, and for health data, in accordance with the NHS Information Security Code of Practice. No disclosive information will be sent by fax or email (unless via GSI for a GSS customer) and, if posted, will be encrypted[7] (using PGP or private crypto – not zipped) to protect the data and despatched by Royal Mail Special Delivery service or by courier.

[7] The standard for NHS generated data is AES 256 bit encryption.

13.4 Hard copies of the data will be stored securely in a locked filing cabinet. Access to the microdata will be restricted to those named on the Data Access Agreement who guarantee to protect and safeguard the confidentiality of the data at all times. Access to data will be via restricted-access password protection.

13.4.1 [Add specific IM security details from proposal]

13 .5 ONS reserves the right to conduct an on-site audit of the beneficiary's confidentiality and security procedures and practices for guaranteeing the security and confidentiality of the data covered by this agreement, or to require the report of such an audit. * (not GSS)

13.5.1. For the purpose of conducting an audit, ONS reserves the right of entry to the premises where the data are stored and processed. * (not GSS)

13.5.2. ONS may require the beneficiary to provide copies of any audits of these arrangements, conducted during the period of the agreement, including any audit implementation plans. * (not GSS)

13.5.3 ONS further reserves the right to attend or audit the destruction of the data at the end of the access period * (not GSS)

13.6 The beneficiary of the data will ensure that access to the data, any copies made of the data and the information contained in them is limited solely to the person who has signed this Agreement and the research team, who are named on this agreement.

13.7 The confidentiality of the data will be preserved in outputs and publications, as detailed in section 5.

13.8 The means of access to the data (such as passwords or pass-phrases) are to be kept secure and not disclosed by the Beneficiary to any individual, under any circumstances

13.9 Data will not be accessed at a private residence nor via any portable device.[8]

14. Breach and Dispute Procedures.

14.1 The breach of any of the terms of this agreement may result in the immediate termination of access to the data and the return of the data to ONS in the manner to be advised by ONS

14.2 The breach of any of the provisions of this Agreement may result in sanctions being sought against the beneficiary. Details of sanctions will be supplied by ONS on request.

14.3 The beneficiary agrees to report immediately to ONS instances of breach of any of the terms of this agreement

14.4 Any disputes arising between the providing and beneficiary organisations will be resolved initially between the principals to the agreement. Otherwise, outstanding issues will be referred to the National Statistician.

[8] Any remote access system would need to be approved by IM security.

15. Approval

The signatories believe this agreement is compliant with the statements of principle in the National Statistics Code of Practice (the Code) and the specific requirements of the Protocol for Data Access and Confidentiality (PDAC). Where this agreement may appear to contradict the statements of principle in the Code or the specific requirements of the PDAC, the Code and the PDAC take precedence, unless explicitly stated.

15.1 Beneficiary Organisation …….

The Responsible Statistician/ Representative for the beneficiary organisation approves the terms of this Agreement and agrees to meet the requirements specified.

Name……..Signature: ……..

Status in the organisation:

Date:

15.2 ONS Approval

The Responsible Statistician for the Office for National Statistics authorises the provision of access to the data to the beneficiary organisation under the terms specified in this Agreement

Name……..Signature: ……..

Status in the organisation:

Date:

PLEASE RETURN TO: EMMA GORDON, ONS, GOVERNMENT BUILDINGS CARDIFF ROAD NEWPORT NP10 8XG