May 2018 (Version 2)

Standard Operating Procedure:

United Kingdom and Ireland Charging Policies for Data Requests

This SOP has been developed by the co-chairs of the UKIACR Analysis Group, Luke Hounsome[1] and Ceri White[2] with important contributions from the UKIACR Executive Committee and UKIACR Analysis group members. The UKIACR Analysis Group will maintain and update this document on an annual basis.

[1]Public Health England Bristol;

[2]Welsh Cancer Intelligence and Surveillance Unit, Cardiff.

Further information on the content of this SOP is available from your regional or national cancer/public health intelligence lead. Their contact details are available from the UKIACR website (http://www.ukiacr.org/).

Contents

Aim

Each country in the United Kingdom and Ireland Association of Cancer Registries (England, Ireland, Northern Ireland, Scotland and Wales) receives a large number of data requests every year. The data requests are welcomed by the registries and reflect the high quality, extended datasets that the registries hold and the skills inherent in the registries to analyse these datasets. Some of these requests are routine and covered by the funding of the Registry while others are more extensive and are not covered by the registry's core funding . In addition there are currently differences in the approach to charging by the registries of the UKIACR. This document aims to bring together the charging policies within the UKIACR for consistency and for information to all UKIACR organisations due to the different overheads and rules of the host organisations. This document will be updated on an annual basis pending any changes in charges for each of the five countries.

If anything here is unclear or you feel that important information has not been included then we would like to hear from you. Please email ceri.white@wales.nhs.uk or luke.hounsome@phe.gov.uk.

Introduction

Data requests are sent to cancer registries in the United Kingdom and Ireland on an ongoing basis. These data requests can take the form of aggregated data, record level data (not identifiable), potentially identifiable data and patient identifiable data. Due to the increasing number of data requests received in each country a cost recovery process has been initiated in some countries. This document details the charging policies for each country for information to stakeholders and for staff members within the UKIACR.

Charging Policies

National Cancer Registration and Analysis Service
Host Organisation- Public Health England- (PHE)

The Office for Data Release (ODR) operates a 3 staged approval process:

- Application
- Assessment and approval
- Access

This process is underpinned by a comprehensive pre-application advice service to enable prospective data users to:

- establish the feasibility of a project and availability of data
- understand methodologies to render data anonymous
- gain access to PHE experts or appropriate collaborators that could assist in the development of an application
- understand what information will be needed to support an application
- understand asset specific application requirements (such as the need for programme level oversight)
- identify potential issues that could lead to delays in access to the data required
- understand the responsibilities of both the applicant and the ODR in applying to access data

It is strongly recommended that prospective applicants discuss their proposed project with the ODR prior to submission of a full application.

Email ODR odr@phe.gov.uk to access pre-application advice.

Applications for data are initiated on submission of a project-specific application form to odr@phe.gov.uk. This includes the ODR data request form and the requisite supporting evidence.

The following pre-application guidance documentation is available:

- ODR data request form
- how to complete the ODR request form

The ODR is also developing a suite of data dictionaries which will be available online in the near future. Please contact the ODR directly to access these resources.

Each application will be acknowledged and receipted and given a unique reference number on submission of a data request. The ODR will manage the application as a project, with an ODR officer coordinating the process and ensuring that all relevant issues are handled appropriately.

The ODR will conduct an initial review of the validity of the request and provide an estimated cost and indicative timescales for delivery following receipt of the application. Estimated times are based on the complexity of the request but on average the ODR aims to finalise a request within 60 working days.

Once the ODR has validated the request, the application will be reviewed to ensure that:

- there is a justified purpose for the release
- the data specification is the minimum necessary and appropriate anonymisation techniques have been applied
- there is an appropriate legal basis for accessing the requested data
- the applicant has appropriate safeguards in place to ensure that the data will be processed safely and securely
- the project will be conducted in line with the Research Governance Framework for Health and Social Care (England) (where applicable) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf
- programme level endorsement has been granted (where applicable)

Conditionally approved applicants will be sent a project-specific data sharing contract determining the permitted processing activities and the terms and conditions of the release. All data will be transferred to an approved data recipient by secure transfer methods once the contract has been signed

PHE follows HM Treasury rules on fees and charges as a publicly funded body. PHE has adopted a formal cost recovery model for the ODR, following approval by the Data Release Assurance Board.

Charges are not levied on the data itself but are recouped to cover the costs of any bespoke data preparation and services.

Estimated costings can be provided and are calculated based on the complexity of the request, data extraction, analysis and presentation tasks involved. Actual costs will be confirmed during the application process and formally agreed before work commences.

Price bands have been identified to give customers a guide of how much their analyses will cost; however, the final cost will be agreed with the customer prior to any work commencing.

Office for National Statistics (ONS)

In addition to tables prepared for the standard outputs produced by Social & Analysis which are covered within the core funding for ONS , bespoke adhoc analyses may be commissioned independently.

Bespoke analyses will be issued to the requesting customer under an Open Government Licence (OGL) by the provision of a link to a URL on the ONS website and are then available free to all other users.

Charging Rates

The cost of the commissioned output reflects the amount of time taken to develop the analyses and undertake all necessary processes in respect of quality and disclosure control. The charges reflect the Full Economic Costs associated with the delivery of the service.

Price bands have been identified to give customers a guide of how much their analyses will cost; however, the final cost will be agreed with the customer prior to any work commencing.

ONS deliver the commissioned outputs within 10 working days of receiving written acceptance of the quote, except in exceptional circumstances. In many cases, where requests are not complex, the outputs can be delivered within 5 working days.

The price bands are set out below:

Band	Time to produce	Charge (Excluding VAT)
A	One hour or less	FREE
B	Up to ½ day	£125
C	Up to 1 day	£250
D	Up to 1 ½ days	£375
E	Up to 2 days	£500
F	More than 2 days	Price on application

All charges are subject to VAT at the standard rate.
Additional advice and guidance may be obtained from cancer.newport@ons.gsi.gov.uk.

Please note that charges for requests which use Annual Survey of Hours and Earnings (ASHE) data will be based on the ASHE charging rates available here: http://www.ons.gov.uk/ons/about-ons/business-transparency/freedom-of-information/what-can-i-request/index.html

National Cancer Registry Ireland (NCRI)

The NCRI do not charge for the extraction/analysis of data requests at present but this is currently under review. However, a charge of €100 per hour is in place for pharmaceutical companies.

Northern Ireland Cancer Registry (NICR)

This policy applies to requests received by the N. Ireland Cancer Registry (NICR) that require new analysis to be undertaken. Some of these are complicated and time consuming and their completion is dependent upon available resources given that priority goes to core business activities for which the NICR receives funding from the Public Health Agency for Northern Ireland (PHA). Depending upon the resource required to undertake such an information request a charge may be applied to recover costs. Requesters will also have to complete the relevant forms for release of such data to ensure compliance with the strict confidentiality rules observed by the NICR. (See NICR Data Release Forms I to V).

These charges will not normally apply to those consumers in the HSC NI family, the Department of Health, Assembly questions or media as the Public Health Agency funding is considered to cover these activities. However, if the request is deemed to be above the normal duties of the NICR or entails significant resources a charge may be applied.
Charges will apply to commercial/private sector, charities and researchers including those from Queen's University Belfast.

Exemptions
The following data requests will normally be provided without charge:

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

We do not charge for the time taken to discuss the exact information requirements, to determine whether we hold the information requested or for the time it takes to decide whether the information is available and can be released.

For all other types of data requests a charge is applied as per the schedule below.

Charges
In the event that we decide to impose a charge we will discuss this with the source of the data request and formally indicate the resource required to provide the data request. If the requestor decides not to proceed with the request there will be no charge applied.
Costs are broken down as follows: (VAT if applicable is additional to these)

- Extraction fee - £100

- Data linkage via Health & Care number (HCN) - £150
- Data linkage where HCN is unavailable - £300 for less than 1,000 records, £400 for 1,000 to 4,999 records, £500 for 5,000 or more records
- Use of facilities 1 year - £200
- Staff time will be charged at the full costs per hour to include salary, NI, pension, overheads etc.

If, however the request is part of a large research project and requires the employment of additional staff then the full cost of the additional staff will be passed on to the research project in question – this cost will be highlighted and agreed in advance.
The final decision on whether to apply charges or accept a data request is subject to management discretion.
All charges are subject to review on an annual basis.

Definitions
A person day = 7.4 hours i.e. if the projected effort required is 14.8 hours this equals 2 person days.

Submission of Requests
Data requests should be submitted on the appropriate request form (See NICR Data Release Forms I to V). The forms are available on the NICR website www.qub.ac.uk/nicr
Applications will be considered by the senior Registry Team within 10 working days of application being received.
Information on the number of requests and relevant costs will be included in annual business plans of the NICR.

Information Services Division (ISD) Scotland

ISD aim to proactively publish data for which there is a wide demand so that it is freely available to all. ISD also releases data through bespoke information products, commonly via the Scottish Health Information Service, to NHS and partner organisations.

Should you require information that requires bespoke new analysis of health and care data held in our national databases this can be requested via our Information Request Service. Our Information Request Service is formally recognised within the NSS Publications Scheme.

Any request which required new bespoke analysis to be undertaken is provided via our Information Request Service. This is dependent upon available resources as priority goes to core business activities for which ISD receives funding from the Scottish Government and NHS and associated bodies. Requests are also subject to ISD's overarching rules relating to statistical governance, and provided that:

- Other information already published or held by ISD, for example a response to a previous information request, is not suitable
- The customer has stated clearly what information they require and if possible why, to enable ISD analysts to understand the request and to provide the most relevant and useful response.

Depending upon the resource required to undertaken an Information Request a charge may be applied to recover costs.

ISD sometimes receive requests for information on aspects of health and care in Scotland with reference to Freedom of Information legislation. Where these cannot be answered using existing or directly available information then ISD will aim to provide the information through the Information Request Service, as detailed above. This may include charging as outlined in ISD's Information Request Service Charging Policy.

Most of the information required by core customers will not be chargeable because it will be part of the normal business activities provided by ISD from central funding. There will be specific circumstances however where requests for ad-hoc work outside these business functions will incur a charge if in excess of the cost threshold. These would include work as part of a commissioned piece of research, new processing and analysing of non ISD data, Independent contractors (e.g. GPs, pharmacists, etc) requesting data or new analysis for another independent contractor, NHS Board etc. In these circumstances work will be subject to negotiation in relation to other priorities and management discretion will apply.

Core customers are defined as public bodies which ISD support as part of our key functions and includes the Scottish Government (SG), NHS Scotland organisations and partner organisations such as Local Authorities and drug agencies, Audit Scotland and independent contractors (dentists, GPs, opticians and pharmacists) seeking data for their own practices.

Complexity Rating

IRs by their very nature will vary both in terms of complexity and the level of skilled statistical expertise required to deliver the requested information. In recognition of this, and in order to remain flexible in responding to requests whilst at the same time delivering our other corporate business commitments, ISD will assess all IRs based on the following complexity ratings.

Standard

The majority of IRs will be assigned a complexity rating of Standard. In essence this rating will encompass basic tabulations or data extracts that require a certain level of skilled statistical expertise in order to extrapolate, manipulate and format the data to meet the customer requirements.

Advanced

IRs will be assigned a complexity rating of Advanced where it is deemed that a higher level of skilled statistical expertise is required to meet the customer requirements. This would include for example the need for record linkage and/or the application of advanced statistical methodologies e.g. the use of modelling techniques, standardisation rates etc.

Thresholds

To minimise the administrative burden in respect of the implementation of the charging policy, a threshold will be applied to IRs. For Freedom of Information requests no charge is applied where the cost of the projected effort required to fulfil a request is less than or equal £100. For the purposes of this policy no charge will be applied where the chargeable time taken to complete the IR is less than a half day, i.e. 3.5 hours (a cost of £135 - £195 depending on the customer and complexity of the request).

The above threshold will be applied in line with the Scottish Information Commissioner's guidance on vexatious or repeated requests.

Application of Charges

Table 1 below shows when charging, based on person days effort, may be applied. The current charging rates can be found in Table 2.

Table 1: Person days effort for core and non-core customers

Person days effort	Core Customers	Non Core Customers
Below Charging Threshold (<3.5 hours)	No Charge	No Charge
<= 2 days	No Charge	Non-core Customer Rate
> 2 days	Core Customer Rate[1]	Non-core Customer Rate

[1] Charging only for work not covered under ISD's normal business activities or central funding. Discuss with line manager before progressing.

IRs estimated to require analytical work costing more than £600 will be deemed to be excessive under this policy and are subject to negotiation.

We do not charge for the time taken to discuss the exact information requirements, determine whether we hold the information requested, nor for the time it takes to decide whether the Information is available and can be released.

In the event that we decide to impose a charge we will issue a notification of the charge (a fees notice) and explain how it has been calculated. There will be three months from the date of issue of the fees notice in which to decide whether to pay the charge to obtain the information. The information will be provided on payment of the charge. If the requestor decides not to proceed with the request there will be no charge applied.

Table 2 provides information in respect of the actual charges that are applicable in respect of IRs. All costs are subject to review on an ongoing basis, but at least annually in line with changes in costs. The latest rates will be published on the ISD website.

The table depicts the day rate that will be applied to an individual IR according to the complexity assigned by the ISD analyst during the initial assessment of the IR.

Table 2: Daily rate for core and non-core customers

IR Complexity Rating	Core Customer Daily Rate	Non-core Customer Daily Rate
Standard (per day)	£270	£335
Advanced (per day)	£315	£390

Notes:
1. The current cost threshold is £100. The time threshold is a half day of chargeable time.

2. No charges will be levied if the cost of producing the IR is less than the Cost Threshold or if less than the Time threshold if this would incur a higher cost.
3. All charges are subject to review on an ongoing basis.
4. A person day = 7 hours i.e. if the projected effort required is 21 hours this equals 3 person days.
5. All charges quoted are the applicable diem rate (day rate) per IR Complexity Rating.
6. All charges quoted in Non-core Customer Daily Rate include the overhead rate.
7. All charges quoted, exclude VAT, which will be applied at the appropriate rate.
8. The final decision on whether to apply charges is subject to management discretion.

The electronic Data Research and Innovation Service (eDRIS) provides a single point of contact to assist in the completion of applications to the Public Benefit and Privacy Panel and assist researchers in study design, approvals and data access in a secure environment. eDRIS aims to make conducting research easier, more efficient and more convenient. eDRIS is part of Information Services Division (ISD) and supports the Farr Institute Scotland, Administrative Data Research Centre (ADRC) and Scottish Government Linkage Projects at No 9 Edinburgh Bioquarter, Little France Road, Edinburgh, EH16 4UX.

Table 3 below shows the current charging policy from eDRIS.

Table 3: Charging policy for eDRIS

NHS / Public sector	**2016/17**	**2017/18**	**2018/19**	**2019/20**
Small Study	£ 4,288	£ 4,352	£ 4,416	£ 4,480
Medium Study	£ 10,720	£ 10,880	£ 11,040	£ 11,200
Large Study	£ 16,080	£ 16,320	£ 16,560	£ 16,800
Compute & Disclosure	£ 1,608	£ 1,632	£ 1,656	£ 1,680
Indexing Support	£ 2,144	£ 2,176	£ 2,208	£ 2,240
Charged according to estimated effort				
Statistical analysis, updates and extracts	-	-	-	-

Academia / Charities	**2016/17**	**2017/18**	**2018/19**	**2019/20**
Small Study	£ 5,576	£ 5,656	£ 5,744	£ 5,832
Medium Study	£ 13,940	£ 14,140	£ 14,360	£ 14,580
Large Study	£ 20,910	£ 21,210	£ 21,540	£ 21,870
Compute & Disclosure	£ 2,091	£ 2,121	£ 2,154	£ 2,187
Indexing Support	£ 2,788	£ 2,828	£ 2,872	£ 2,916
Charged according to estimated effort				
Statistical analysis, updates and extracts	-	-	-	-

Commercial / Industry	**2016/17**	**2017/18**	**2018/19**	**2019/20**
Small Study	£ 12,864	£ 13,056	£ 13,248	£ 13,448
Medium Study	£ 32,160	£ 32,640	£ 33,120	£ 33,620
Large Study	£ 48,240	£ 48,960	£ 49,680	£ 50,430
Compute & Disclosure	£ 4,824	£ 4,896	£ 4,968	£ 5,043
Indexing Support	£ 6,432	£ 6,528	£ 6,624	£ 6,724
Charged according to estimated effort				
Statistical analysis, updates and extracts	-	-	-	-

For further information regarding eDRIS please see http://www.isdscotland.org/Products-and-Services/eDRIS/

Welsh Cancer Intelligence and Surveillance Unit

Any data request received internally within the NHS, Welsh Government and ONS are provided free of charge.

Any data request received externally to the NHS and the analytical time taken to extract and analyse the data is less than one hour is provided free of charge. Data requested to participate in International or European studies e.g. Eurocare 6, CONCORD 3, Cancer in Five Continents are also exempt from charge. For all other types of data requests a charge is applied.

The internal WCISU Research and Data Request Group (RDRG) meet on a monthly basis. At these meetings any new data requests received since the last meeting are considered, and actions decided. A completed data request form is required for a case to be discussed at the meeting (Appendix 1) along with an administration charge of £90 + VAT and should be received before discussed at the meeting. For ongoing cases, any additional information received is considered and further actions are agreed. For record level data (including patient identifiable and no patient identifiable data) and for some aggregated data counts that have been discussed at the meeting then a data sharing agreement must be completed and signed between the Welsh Cancer Intelligence and Surveillance Unit and the requestor's organisation before any data is sent. Additionally, the data requestor should send any relevant information necessary e.g. a copy of the CAG approval or ethics approval before we can approve a data request.

Table 3 summarises the costs administered at the WCISU.

Table 3: Data request costs at the WCISU

Type of applicant	Initial request review	Data and analysis work
• Internal ○ Welsh Government ○ NHS Wales ○ ONS ○ Health Boards ○ Clinicians	**No Charge**	**No Charge**
• External ○ 3rd Sector ○ Academia ○ Media ○ General public	**£100.00 + VAT**	**Charges assessed on a case by case basis in line with resources required**

The data and analysis work for external data requests is based on the person carrying out the data extraction/analysis and is based on the following:

- Band 5, mid point £16.22 per hour
- Band 7, mid point £26.89 per hour
- Band 8a, mid point £31.31 per hour

There is a minimum charge of 2 hours due to the quality checking of the original data extractor/analyst.

All completed data request forms can be sent to the generic WCISU email address WCU.Stats@wales.nhs.uk or sent to the director (dyfed.huws@wales.nhs.uk) which will then be discussed at future meetings. Current dates of future meetings are as follows but are subject to change:

- 30th May 2018
- 13th June 2018
- 24th July 2018
- 22nd August 2018
- 24th September 2018

The data sharing agreement will state an expiry date of a year unless specifically requested for a longer duration and so the data should be destroyed after this date. For annual refreshes of data the latest extract should replace the one that was previously requested and a completed data destruction certificate should be completed and returned to WCISU. This certificate will be sent automatically to the requestor when the expiry date has passed.

Further information

Further information regarding data requests can be found via the following websites:

England: http://www.ncras.nhs.uk/phe-office-data-release-odr/

ONS: https://www.ons.gov.uk/aboutus/whatwedo/statistics/requestingstatistics/makingarequest

NCRI: http://www.ncri.ie/data/data-request

NICR: https://www.qub.ac.uk/research-centres/nicr/CancerInformation/requests/

WCISU: http://www.wcisu.wales.nhs.uk

Appendix A: Data request form to be completed to the Office for Data Release

Public Health England

Protecting and improving the nation's health

ODR Data Request Form (May 2017 v3.0)

Overview
Applicants are advised to read the supporting guidance prior to completing this form to fully understand what information should be submitted to the Office for Data Release (ODR). Details given will be used to review your application for data from Public Health England (PHE) and will form part of the data sharing contract. Please complete all relevant fields and include all the required documentation. Note: incomplete application forms will delay the approval process.

Section 1: applicant and organisation information (mandatory)

All fields in this section must be completed. The applicant should be the individual who has overall responsibility for the project (for example the principal investigator or audit lead).

Applicant:	
Title:	
First name:	
Surname	
Job title:	
Email address:	
Contact telephone number:	
Applicant's organisation:	
Organisation name:	

Registered organisation address:				
Organisation type:	Academic institution (UK)	☐	Local authority	☐
	CQC-registered health or/and social care provider	☐	CQC approved national contractor	☐
	Government agency (health and social care)	☐	Government agency outside of health and adult social care	☐
	Commercial	☐	Independent sector organisation	☐
	Other			

Section 2: funding and sponsorship (where applicable)

Complete the name and address of any funder or sponsor for this project. If both apply but these are two separate organisations, please include details for both, labelled appropriately (as sponsor or funder).

Funder/sponsor:	
Name and address of awarding institution:	
Reference for project/activity:	

Section 3: project summary (mandatory)

All fields in this section must be completed. See guidance for more information.

Project summary:

ODR reference:	Insert any ODR reference assigned for this project. Leave blank if new project.			
Data sharing contract reference:	Reference any data sharing contract held with PHE for this project. Leave blank if new project.			
Project title:				
End-use: See information here *(hyperlink)* for defining research and other types of projects.	Research	☐	Service evaluation	☐
	Clinical audit	☐	Surveillance	☐
	Other, please specify			
Provide a summary of the project's aims, objectives, methods and anticipated outputs. **This summary must be understandable to a lay audience. Guidance on this is available here** *(hyperlink)***.**				
Do you intend to use the data provided to contact anyone? If yes, please give details.				
Please indicate the estimated project start date and project duration (months): Data sharing contracts issued by the ODR are for a default term of twelve months. If you require data for longer than this, please indicate and justify.				
Data already held for this project/purpose: Please include the dataset name, classification of the data (eg identifiable), the legal basis for processing, and the dataset period.				

Section 4: data specification (mandatory)

All fields in this section must be completed. See guidance for more information.

Data specification:		
Classification of data requested (please select appropriate classification):		
The data is stripped of direct identifiers and techniques such as suppression, offsetting and aggregation are applied to render the data anonymous in line with the ISB Anonymisation Standard for Publishing Health and Social Care Data. The residual risk of re-identification is negligible or very low. Where possible, data will be released under an Open Government Licence with no further control.	**Anonymised**	☐
The data is stripped of direct identifiers but contains fields which could be used to indirectly identify an individual through combinations of information, either by the people handling the data or by those who see published results (eg ethnicity, sex, month and year of birth, admission dates, geographies or other personal characteristic). The data will be released with controls in line with the ICO Anonymisation Code of Practice.	**De-personalised**	☐
The data request includes direct identifiers (eg name, address, NHS number, date of birth, date of death) or is coded (pseudonymised), but would be directly identifiable in the hands of the data recipient (such as by hospital number or a cohort-specific identifier). To access identifiable data, an extant legal gateway must be presented (see Section 6). Data will be released with controls.	**Personally Identifiable**	☐

Please indicate the dataset(s) needed for the processing activities:	**Bespoke extract**	**Tabulation**	**Linkage**
National cancer registration and analysis service	☐	☐	☐
National congenital anomaly and rare disease register	☐	☐	☐
National drug treatment monitoring dataset	☐	☐	☐
Abdominal aortic aneurysm screening	☐	☐	☐
Bowel cancer screening	☐	☐	☐
Breast cancer screening	☐	☐	☐

Cervical cancer screening		☐	☐	☐
Diabetic eye screening		☐	☐	☐
Fetal anomaly screening		☐	☐	☐
Infectious diseases in pregnancy screening		☐	☐	☐
Newborn and infant physical examination screening		☐	☐	☐
National newborn blood spot screening		☐	☐	☐
Newborn hearing screening		☐	☐	☐
Sickle cell and thalassaemia screening		☐	☐	☐
Hospital Episode Statistics	Admitted Care			☐
	Accident and Emergency			☐
	Outpatient			☐
Mortality (ONS)				☐
Other (specify)				
Specify any data linkage requirements including the required data flows between PHE and the other organisations to be involved. (Where there are multiple data linkages required, involving two or more data processors, the protocol must include a diagram to illustrate the proposed data flows. Please ensure each organisational boundary is clearly identified and where identifiable data is moving between organisations, those fields are also included. See guidance for more information and an example data flow diagram.)				
Frequency:	One - off	☐		
	Periodic - monthly	☐		
	Periodic - quarterly	☐		
	Periodic - annually	☐		

	Other			
Preferred form for receipt of data:	Excel	☐	ASCII	☐
	Other (Specify):			
Is there a deadline for receipt of data: Please give date and reason:				

Section 5: PHE programme-level support (where applicable)

All fields in this section may be completed. See guidance for more information.

Programme support:	
Has programme support been sought/ granted? If so, from which?	
Programme approval reference:	
Date of programme approval: If already obtained, include your approval letter and any relevant correspondence with your application.	
Please identify any contacts within PHE your request has been discussed with:	

Section 6: legal gateway to process personally identifiable data (mandatory for any request for personally identifiable data, including name, address, postcode, date of birth, date of death or free text)

To process patient identifiable data, an exemption to the common law duty of confidence must be evidenced. Indicate the legal gateway under which identifiable data will be processed by the applicant or data processor, acting on the directive of the applicant. Where more than one exemption applies, please provide evidence of each.

Legal gateway:				
Direct care The Caldicott Review *(hyperlink)* defines 'direct care'; see guidance.	☐	Please enclose evidence of Caldicott guardian or other approved signatory support for processing the data for the purpose(s) outlined above. See ODR Guidance for more information. ☐I have enclosed a signed letter from my Caldicott guardian Caldicott guardian name:		
Informed patient consent	☐	Please enclose a copy of a blank consent form and any associated patient information documents with this form.		
Section 251 exemption	☐	Please enclose all letters documenting that Section 251 support has been granted and remains extant, sent to you by the Health Research Authority for this project. ☐ **I have enclosed a copy of the S251 approval, approved amendments and any renewal letters**		
	CAG reference:		**Date of approval:**	**Date of next renewal:**
Regulation 3, Health Services (Control of Patient Information) Regulations 2002	☐	**Please contact the ODR to discuss.**		

Section 7: legal gateway to process ONS mortality data (required, where relevant)

Indicate the legal gateway held to process ONS mortality data. Note: this section is not applicable to linked cancer registry-mortality data.

Legal gateway to process ONS mortality data:	
Informed patient consent	☐
s42(4) of the SRSA 2007 amended by s287 of the Health and Social Care Act 2012	☐
Approved researcher accreditation	☐

Section 8: ethics approval for research (mandatory for all research projects where the request is to process de-personalised or personally identifiable data)

All fields in this section must be completed. See guidance for more information.

HRA Research Ethics Service *(hyperlink)* approval (for research requests only):			
Has ethics approval been obtained and from whom?	**HRA REC name:**		
	HRA REC reference:		☐**I have enclosed a copy of the final REC approval letter**

Section 9: applicant's organisation: information governance, data management and security assurances (mandatory)

All fields in this section must be completed. See guidance for more information.

Information governance management (The applicant must ensure anyone who has access to the data understands their responsibilites for confidentiality, data protection and information security and is left in no doubt about the consequences of misconduct. The applicant must certify the following organisational information governanace requirements have been met)	
• I certify that the individual(s) who will process the data is a/are *bona fide* worker(s) at the applicant's organisation (Section 1).	☐
• I certify that the individual(s) (including permanent, temporary and locums) who is/ will process the data has/have been subject to personnel background checks and their employment contracts include compliance with organisational information governance standards.	☐
• I certify that information governance awareness and mandatory training procedures are in place and the individual(s) who is/ will process the data is/are appropriately trained.	☐
• I certify that the data can be entrusted to the organisation, in the knowledge that the individual(s) processing the data will conscientiously discharge his/her/their obligations, including with regard to confidentiality of the data.	☐

Confidentiality and data protection assurance(s):				
Territory of processing	UK	☐	EEA	☐
	Other			

Fair processing assurances [insert details of your organisation's registration with the ICO on the Data Protection

Public Register *(hyperlink)*]			
DPA registration (code and register organisation name):		[Provide the organisation code and name (as registered)]	
DPA registration expiration date:			
Security assurance (provide one of the following)			
Information Governance Toolkit *(hyperlink)*	☐	Organisation code and score:	Version and date completed:
ISO 27001	☐	(Please enclose a copy of the certificate)	
SLSP	☐	(Please enclose a completed system level security policy for ODR review. A template is available upon request.)	

Section 10: outsourced organisation: information governance, data management and security assurances (mandatory if any processing activities will be outsourced).

All fields in this section must be completed. See guidance for more information.

Data Processor: identify any organisations that data processing will be outsourced to (ie any company/organisation acting on the instruction of the applicant).	
Organisation name:	
Organisation address:	
Information governance management (The applicant must ensure the outsourced organisation(s) understands their responsibilites for confidentiality, data protection and information security and left in no doubt about the consequences of misconduct. These responsibilities must be established through contractual controls with the outsourced organisation).	

- I certify that a Data Processing Contract, enforceable in the UK, has been executed with the Data Processor (named above) and is compliant with the ICO Guidance on ☐

Outsourcing. *A copy of the Data Processing Agreement MUST be shared with the ODR.*

- I certify that the Data Processing Contract provides an explicit directive to the Data Processor to process the data for a specific, time-limited purpose. ☐
- I certify that appropriate due diligence has been undertaken to ensure: ☐
  - Only *bona fide* worker(s) at the outsourced organisation will process the data.
  - All employees of the outsourced organisation, who will process the data, including permanent, temporary and locums, have been subject to personnel background checks and their employment contracts include compliance with organisational information governance standards.
- All employees of the outsourced organisation who will process the data have undertaken information governance awareness and mandatory training procedures are in place and all individuals who will process the data are appropriately trained. ☐
- I certify that the data can be entrusted to the Data Processor, in the knowledge that the Data Processor data will conscientiously discharge his/her/their obligations, including with regard to confidentiality of the data. ☐
- I certify that adequate breach notification arrangements are in place. ☐

Confidentiality and data protection assurance(s):				
Territory of processing:	UK	☐	EEA	☐
	Other, specify			

DPA registration *(hyperlink)* **code and register organisation name:**	[Provide the organisation code and name (as registered)]
DPA registration expiration date:	
Security assurance (please provide one of the following)	

Information Governance Toolkit *(hyperlink)*	☐	Organisation code and score:	Version and data completed:
ISO 27001	☐	(Enclose a copy of the certificate)	
SLSP	☐	(Enclose a completed system level security policy for ODR review)	

Section 11: expected outputs and dissemination of results (mandatory)

All fields in this section must be completed.

Expected outputs. Please identify the type of outputs this project with produce:			
Internal meeting	☐	External meeting	☐
Internal report	☐	External report	☐
Conference	☐	Publication	☐
Other (please specify)			
The applicant must acknowledge the intellectual, scientific and professional contributions PHE employees have made/will make to their project through co-authorship and recognition as non-author contributor, as appropriate, on any publication they will produce from the data.			

Section 12: any additional information

Section 13: declaration (mandatory)

The information contained in this application form is true, correct and complete. I understand that any misrepresentation may invalidate my application or lead to delay in access to data:	
Signature:	
Date:	

Appendix 1: accompanying documentation/evidence (mandatory)

Materials submitted	Submitted	File name and version

Protocol	☐	
Data specification(s) - **including inclusion / exclusion criteria**	☐	
REC approval - **NREC approval letter(s)**	☐	
Legal gateway to access patient identifiable data		
Direct care - **signed declaration from approved signatory**	☐	
Consent - **blank consent form** - **patient information**	☐	
Regulation 3 (Section 251)	☐	
Regulaton 5 (Section 251) - **IRAS form** - **CAG approval letter(s)** - **CAG renewal letter(s)**	☐	
Contact documents		
- **patient/GP letters**	☐	
- **other contact documents**	☐	
Legal gateway to access ONS mortality data		
- **ONS approved researcher accreditation**	☐	
Security assurances		
- **ISO 27001 certificate** - **system level security policy**	☐	
Other		
List any other supporting documents	☐	

PHE publications gateway number: 2017105. Published: June 2017.

Appendix B: Data request form to be completed from the Welsh Cancer Intelligence and Surveillance Unit

Patient Identifiable or Potentially Identifiable

DATA REQUEST FORM

GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales

Welsh Cancer Intelligence and Surveillance Unit
Uned Gwybodaeth a Gwyliadwriaeth Canser Cymru

IMPORTANT – PLEASE READ

About this form

This form is an application for data. It does not guarantee that the Welsh Cancer Intelligence and Surveillance Unit will release the data; completion of this data request form together with the associated application charge for consideration will aid this decision.

Charges

The Welsh Cancer Intelligence and Surveillance Unit operates on a cost recovery basis, where the costs of administration for supplying data are not fully covered by those statutory duties. The Welsh Cancer Intelligence and Surveillance Unit does not seek to make an operating profit from providing these services. A charge of £100 + VAT is made for a data request application to be considered and discussed at the Welsh Cancer Intelligence and Surveillance Unit Research and Data Request Board. Please note this will not necessarily result in your application being successful. An additional charge, to be determined, is also required if successful depending on the data extraction time.

Data items

Although there are many data items listed, under law we are obliged to restrict data release to the minimum required for your study, at the highest level of anonymisation possible.

Since the Office for National Statistics are the legal owners of death information in England and Wales, they are required to authorise the release of such data by the Welsh Cancer Intelligence and Surveillance Unit. Therefore, the requestor is required to ask the Office for National Statistics at cancer.newport@ons.gsi.gov.uk to create a data access agreement to allow the release of death data by the Welsh Cancer Intelligence and Surveillance Unit.

Please request only the data items that you actually need for the requirements of your work. Do not request additional data items.

Publication

If you intend to publish works containing the data in any form, please consult the Welsh Cancer Intelligence and Surveillance Unit.

Caldicott Guardian informed

A signed copy of this request form will be forwarded to the Caldicott Guardian for Public Health Wales for the data requested. Where the recipient is based at another organisation than that of the data requested, a further copy may be forwarded by the Welsh Cancer Intelligence and Surveillance Unit to the Caldicott Guardian of that organisation.

ACCOMPANYING DOCUMENTS

Research, audit or service evaluation

If requesting data for research, audit or service evaluation a copy of your study protocol should also be attached, if applicable.

For research, when requesting identifiable or potentially identifiable data, you should also include a copy of the appropriate ethics committee approval. For identifiable data, proof of health research authority CAG approval or evidence of patient consent should also be included.

Declaration

Applicant must sign declaration on page 3 in all cases, but the level of identifiable data requested will determine which (if any) co-signatory is required.

Return form to address shown below by post or a scanned copy by email.

Address:	Public Health Wales, Welsh Cancer Intelligence and Surveillance Unit, Floor 5, Number 2 Capital Quarter, Tyndall Street, Cardiff, CF10 4BZ		
Telephone:	02920 373500	email:	wcu.stats@wales.nhs.uk

CONTACT DETAILS

Person to whom data are to be released	
Title	
Full Name	
Job Title	
Organisation	
Address (work)	
Postcode	
Telephone	
email	

Public Health Wales, Welsh Cancer Intelligence Unit (WCISU), Data Request Form v3

STUDY DETAILS

Purpose

Please state the purpose for which data are required (including an explanation of why non-identifiable data will not meet your needs). Please attach your study protocol, if relevant.

Scope - ☐ UK country/ ☐ UK national / ☐ International ☐ Multi-Regional/ ☐ Single Region

DATA REQUIREMENTS

Data range required

Please describe the cohort of data required

☐ **Tumour site(s)** and/or ☐ **Morphologies**
Please specify ICD 10 codes

Sex - ☐ Male / ☐ Female / ☐ Both

Years of - ☐ Diagnosis / ☐ Death / ☐ Treatment

☐ **Geographical areas** / ☐ **Organisations** (e.g. Health Board / Trust, Lower Super Output Area, Middle Super Output Area, Hospital, etc...):

Age Groups - ☐ 5 Year Groups (0-4, 5-9 ...80-84, 85-89, 90+)
or ☐ Other (specify)

Any other details (please continue on page 4 if necessary)

Is there a deadline for receipt of data?

☐ YES / ☐ NO - If yes, please give date and reason:

Please note that this is not meant to be an exhaustive list, but primarily a tool, intended to open a dialogue between the applicant and the Welsh Cancer Intelligence and Surveillance Unit.

Although there may be capacity to collect all of these data items, they are not always recorded. The Welsh Cancer Intelligence and Surveillance Unit will advise you about the completeness of these variables in relation to your request.

For example, some data items may only be available only for specific cancer sites or recent years. It may be possible to extract further details if these exist (e.g. treatment types or dates). Please consult the Welsh Cancer Intelligence and Surveillance Unit for advice.

Data items required

☒ **Please check items required - only the identifiers and data items that are essential for the requirements of your work**

Personal details

- ☐ **NHS Number**
- ☐ **Patient Name** (Surname, Forename, Initials)
- ☐ **Surname at Birth** (previous surname)
- ☐ **Address** (at time of diagnosis)
- ☐ **Sex**
- ☐ **Date of Birth**
- ☐ **Age** (at diagnosis)
- ☐ **Postcode** (at time of diagnosis)

Various geographies can also be derived from postcode:

- ☐ *Health Board*
- ☐ *Local Authority*
- ☐ *ONS Super Output Area*
- ☐ *Deprivation Index*

Diagnostic, tumour and treatment details

- ☐ **Site** of primary neoplasm (or main presenting secondary when primary site is not known)
- ☐ **Morphology** (type of neoplasm)
- ☐ **Laterality** (side) for paired organs
- ☐ **Stage** (limited information available)
- ☐ **Grade** of tumour (degree of differentiation – available for breast and cervical cancer)
- ☐ **Basis of Diagnosis** (histology, cytology, clinical)
- ☐ **Date of Diagnosis**
- ☐ **Year of Diagnosis**
- ☐ **Treatment Indicators** (treatment within first six months after diagnosis where available)

Hospital details of point of diagnosis

- ☐ **Hospital** ☐ **Health Board/Trust**
- ☐ **Consultant** (surname, initials, specialty, GMC code)
- ☐ **Unit number** (Patient Administration Number)

Death details

- ☐ **Alive/Dead**

ONS Data Access Agreement required to receive this data

- ☐ **Date of Death**
- ☐ **Death Cause**

Public Health Wales, Welsh Cancer Intelligence Unit (WCISU), Data Request Form v3

CONFIDENTIALITY/ETHICS APPROVAL

Identifiable Data Requests

☒ **Please check all boxes that apply and give any further details in the space provided**

HRA Confidentiality Advisory Group (CAG)

The health research authority CAG considers the use and transfer of identifiable patient data under the Health and Social Care Act 2012

(http://www.hra.nhs.uk/resources/confidentiality-advisory-group/) Identifiable data cannot be released without either (A) patient consent or (B) CAG approval, except to (C) authorised personnel in approved organisations – please see the guidance notes for further information.

For identifiable data (only) please indicate consent:

Consent type obtained (please complete relevant sections)
☐ (A) Patient consent ☐ (B) CAG approval ☐ (C) Other approved signatory

A - Individual Patient Consent

☐ I have received proof of written consent for all patients

☐ I have enclosed a copy of a blank consent form and associated documentation, to which all patients have agreed.

B - CAG Approval

Has CAG approval been given?
☐ *Yes* ☐ *No* ☐ *Application submitted*

☐ I have enclosed copies of the application and the approval letter *(essential before data can be considered)*

If application submitted, please give an indication of when approval is expected:	
If available, please give the CAG reference code:	

Identifiable and Potentially Identifiable Requests

Ethical Committee Approval (for research requests only)

Has ethical committee approval been given?
☐ *Yes* ☐ *No* ☐ *Application submitted*

Type of approval sought	☐	*MREC*	☐	*LREC*

REC name

☐ I have enclosed copies of the application and the approval letter *(essential before data can be considered)*

If application submitted, please give an indication of when approval is expected:	

USE OF DATA

Use of Identifiable Data to Contact Individuals

Do you intend to use the data provided to contact anyone? (see note 5 of DECLARATION opposite)

☐ *Yes* ☐ *No*
☐ *Treating clinicians* ☐ *Pathologists*
☐ *Patients' GPs* ☐ Other *(please specify)*

☐ I have enclosed copies of the letters to be used for contact *(essential before data can be considered)*

Dissemination of Results (all types of data)

Please specify your intentions to publish:

☐ *Internal meeting* ☐ *External meeting*
☐ *Internal report* ☐ *External report*
☐ *Conference* ☐ *Other (please specify)*
☐ *Publication*

Please give full details of the name of meeting/conference (or title of report/publication):

Applicant – This must be the Principal Investigator(s) or the most senior person accountable for research

Signature	
Date	
Designated Signatory (see Guidance Notes)	
Title / Full Name	
Job Title	
Organisation	
Capacity signing under (see page 6)	
Signature	
Date	

Purchase order number for application charge:

Public Health Wales, Welsh Cancer Intelligence Unit (WCISU), Data Request Form v3

ADDITIONAL INFORMATION

Any other information in support of your application

Patient Identifiable or Potentially Identifiable Data

GUIDANCE NOTES

CONFIDENTIALITY GUIDELINES

Disclosure of Identifiable Data (or potentially identifiable information*) by the Welsh Cancer Intelligence and Surveillance Unit:

Regulation 2 of the Statutory Instrument (SI) on confidentiality – No. 1438, The Health Service (Control of Patient Information) Regulations 2002 – permits cancer registries and organisations fulfilling this role to receive patient identifiable data without the need for informed consent and it permits these organisations to process said data for the medical purposes stipulated in regulation 2.

Identifiable patient data

Identifiable data is that which includes any of the following: name, address, postcode, date of birth, date of death, NHS no, hospital no.

Potentially identifiable data

Potentially identifiable data is that which does not contain explicitly identifiable data, but does contain low level or small number data that, in some circumstances, might lead to the identification of individuals.

*** As a general rule, the following categories should be regarded as being potentially identifiable data:**

1. Individual records even if they do not include variables, such as names, full postcodes, and dates of birth which would make them obviously identifiable. Full guidance on potentially identifiable record level data can be found in the HSCIC anonymisation standard: http://www.isb.nhs.uk/documents/isb-1523/amd-20-2010/index_html
2. Tabular data, based on small geographic areas**, with cell counts of fewer than five cases/events (or where counts of less than five can be inferred by simple arithmetic)
3. Tabular data containing cells that have underlying population denominators of less than 1,000

**** As a general rule, the following categories should be regarded as small geographic areas:**

1. Those areas where the total denominator population is less than 60,000 persons, e.g. LSOAs or aggregation of LSOAs. This gives a total population of 1500 (if divided into 40 single sex, 5-year age group assuming an equal size distribution).
2. Any geographic area (e.g. local authority) which, when released, may provide information regarding small population non-contiguous areas ("slivers") when combined with CCG or other geographic information. These should be regarded in the same way as ward level data
3. Any geographic area when publication in five-year age groups between 0 and 24 years is required. In this age range, particular scrutiny should be paid to tabulations and appropriate aggregations used. (Due to the rarity of cancer in children and young adults, there may be a non-negligible risk of information disclosure by for any geographic area).

Public Health Wales, Welsh Cancer Intelligence Unit (WCISU), Data Request Form v3

CONSENT FOR RELEASE OF DATA

Appropriate Signatories - Designated Individuals
Wherever possible, a registered health professional should sign requests for the cancer registration information. We recognise that people with other training are appointed to some of these posts; for example, directors of Public Health, where they could reasonably be expected to sign *ex officio*. Possible signatories for the different organisations requesting different types of data are listed below, but their inclusion does not necessarily mean that anyone or only one of them can sign for a given request. The Welsh Cancer Intelligence and Surveillance Unit will use its discretion as to who should sign, and for some requests, several signatories may be needed. For some purposes, signatories may be specified in Service Level Agreements between Public Health Wales and particular organisations.

Type of Data	Possible Signatories
NHS	
Clinician's own data or data regarding patients of predecessor	Clinician (needs to sign stating taken over care of patients from predecessor) Caldicott Guardian (for patients not now managed by any clinician in trust) Medical Director (for patients not now managed by any clinician in Health Board / Trust)
Cancer Site-Specific data	Lead Cancer Clinician Lead Tumour Site-Specific Clinician Health Board / Trust's Lead Clinician for Audit (if data request stated for audit) Caldicott Guardian Medical Director
Data for the whole Health Board/Trust	Lead Cancer Clinician Health Board / Trust's Lead Clinician for Audit (if data request stated for audit) Caldicott Guardian Medical Director
Data for Split Site Health Board/Trust/ Cancer Centres	Lead Cancer Clinician from each unit Health Board / Trust's Lead Clinician for Audit from each unit (if stated for audit) Caldicott Guardian from each unit Medical Director from each unit
Private Hospital	
Clinician's own data	Clinician
All hospital/unit: only the data they sent us if possible (assumed purpose is audit)	Signatures of all Clinicians of patients involved Medical Director
All NHS Health Boards/Trusts they serve for pathology cases only, and only the data they sent us if possible	Senior Pathologist / Clinical Head of Pathology Service Caldicott Guardian from each of the Health Boards / Trusts Medical Directors from each of the Health Boards / Trusts
Private Pathology Laboratory	
Own pathology patients only, and only the data they sent us if possible	Head of Pathology Service
Hospice	
Own patients – complete records	Signatures of all Clinicians Medical Director
GP Practice	
Own patients – either at diagnosis or registered at time of request	Lead GP for Cancer Signatures of all GPs Head of Practice Caldicott Guardian
Screening Services Wales	
Relevant patients – screening age groups	Covered by Service Level Agreement
Cancer Network(s)	
All Network – either patients diagnosed or treated in the network or for cases resident in the network geographical boundaries	Network Lead Cancer Clinician Network Lead Clinician for Audit (if data request stated for audit)
Multi-Disciplinary Team – either patients diagnosed or treated in the network or for cases resident in the network geographical boundaries	Network Lead Cancer Clinician Network Lead Tumour Site-Specific Clinician Network Lead Clinician for Audit (if data request stated for audit) Signatures of all Clinicians in the MDT Lead Clinician for the MDT
Cancer site-specific data – either patients diagnosed or treated in the Network or for cases resident in Network geographical boundaries	Network Lead Cancer Clinician Network Lead tumour Site-Specific Clinician Network Lead Clinician for Audit (if data request stated for audit)

Appendix C: Data sharing agreement template to be completed and signed for data requests between the Welsh Cancer Intelligence and Surveillance Unit and requestor

Data Sharing Agreement

Introduction

This data sharing agreement has been written in accordance with the guidelines contained within the Wales Accord on the Sharing of Personal Information (WASPI) and the NHS Wales guidance on Information Sharing.

Purpose

This data sharing agreement has been drawn up for the Welsh Cancer Intelligence and Surveillance Unit (WCISU) of Public Health Wales to pass on identifiable or potentially identifiable data relating to individuals in Wales with a cancer registration for [insert cancer and ICD 10 codes here] to the [insert organisation name here].

This data will be used for [insert reason here – from protocol].

If during the period of agreement additional uses of the data are identified, these should be notified to the Welsh Cancer Intelligence and Surveillance Unit for agreement.

Organisation details

This data sharing agreement is drawn up between

(1) The WCISU, Public Health Wales, 5th Floor, No 2 Capital Quarter, Tyndall Street, Cardiff, CF10 4BZ.

and

(2) [insert organisation name and address here]

hereinafter collectively referred to as the "Parties".

[Insert organisation name here] may only use the information disclosed to them under this agreement for the specific purpose(s) set out in this document. The information will

not be shared with, or passed to, any third parties without prior approval of the originating partner.

Period of agreement

This agreement commences on [insert date] and will terminate on [insert date] unless extended by the mutual agreement of both parties in writing, at which point an amendment will be issued by the WCISU to replace this document. If required, this agreement will be subject to formal review on an annual basis.

Data required

The following data items have been authorised for release:
[insert list of data items]

Permissions

[insert relevant permissions here e.g. CAG/Ethics references/NHS Research Permissions]

Transfer of data

Before transfer of data the WCISU will encrypt the spreadsheet using WINZIP '256-bit AES encryption' with a password length of at least 10 characters which MUST include numbers, letters and symbols and should be a mix of upper and lower case characters. The data will be sent via a secure file sharing platform, MOVEit DMZ. MOVEit DMZ has its own built-in, FIPS 140-2 validated 256-bit AES encryption that it uses to automatically safeguard each file it receives. Each encrypted file has its own key, which is also encrypted. Hackers cannot access files stored by MOVEit DMZ.

Security arrangements

The [insert organisation name] formally wishes to acknowledge its explicit commitment to maintaining the confidentiality, safety, security and integrity of all confidential and sensitive data to which the organisation is privy and which may be held under its guardianship. The [insert organisation name] continues to legitimately enter into formal agreement and/or implicit undertaking with all its clients, staff, visitors, suppliers and others, in recognition of the fact that the data is held under the guardianship of the [insert organisation name] and which is pertinent to the individual client, staff member, visitor, supplier and/or other, will only be used for the explicit agreed purpose or purposes for which it has been provided, and that there will be no unlawful disclosure or loss of the same.

Users of the data supplied are obliged to fully comply with the Data Protection Act 1998, together with all other related and relevant legislation and Department of Health directives covering issues of data sharing and including:

- British (International) Standard ISO 27001;
- The Caldicott Report 1997;
- The Freedom of Information Act 2000;
- Section 251 of the Health and Social Care Act 2006;
- Confidentiality: NHS Code of Practice 2003;
- NHS Records Management Code of Practice (Part 1, 2006 & Part 2, 2009);
- The NHS Information Security Management Code of Practice 2007;
- The Computer Misuse Act 1990;
- The Electronic Communications Act 2000;
- The Regulation of Investigatory Powers Act 2000;
- The Copyright, Designs and Patents Act 1988;
- The Re-Use of Public Sector Information Regulations 2005;
- The Human Rights Act 1998;
- NHS Care Record Guarantee 2007;
- The Data Protection (Processing of Sensitive Personal Data) Order 2000;

Data retention and data destruction

The data will be retained until the end date of the agreement (or relevant review period where appropriate). Extension of the retention period is subject to a formal review with any amendments jointly/formally agreed.

On completion of the work, system data will be securely destroyed using proprietary file shredding software and the WCISU will be notified accordingly. Physical media will be destroyed using a file shredder or confidential paper disposal firm and confirmation that this has occurred will also be given in writing to the WCISU.

Breach of conditions

The [insert organisation here] agrees to report immediately to the WCISU instances of breach of any of the terms of this agreement.

Variation of this agreement

Both parties have the right to request a change in terms of this agreement and notify the other party in writing. On such occasions the agreement will continue under the existing terms until such time that any revisions have been agreed.

If the person signing for the [insert organisation here] should leave their post or the responsibility for this agreement changes from them, then it is incumbent on that person to arrange a new signatory to this agreement and inform the WCISU immediately. An amendment to the agreement will then be drafted and signatures sought.

Intellectual Property

No contact will be made with any individual identified or their relatives or associates in the information supplied without the prior approval of the WCISU. The information will not be released to any other individual(s) or organisation(s) not directly connected with the work specified without prior approval of the WCISU except in the form of non-disclosive statistical tables or conclusions. The WCISU must be notified of any further studies that the requested data may be used for other than that stated here.

Any report or document produced (e.g. internal, external, peer reviewed journals etc...) from this work using the WCISU data must acknowledge the WCISU clearly in writing within this report i.e. "Source: Welsh Cancer Intelligence and Surveillance Unit, Health Intelligence Division, Public Health Wales" as a minimum. Notification and pre-public viewing of the final document is required at least 30 working days before publication.

The WCISU bears no responsibility for the further analysis or interpretation of the data supplied to [insert organisation here].

Data return

There may be situations where the WCISU would require the data in its processed form to be returned or the results of the work undertaken (if required by Public Health Wales when a report/document is not generated).

Charges

The WCISU operates on a cost recovery basis, where the costs of data administration under this data sharing agreement are not fully covered by those statutory duties which are covered by its central organisation funding. The WCISU does not seek to make an operating profit from providing services under this data sharing agreement. A charge of £ [insert cost here] will be recouped for the administration of this data. A purchase order is required prior to data release.

Special conditions

[Insert here]

Agreement signatures

For and on behalf of the WCISU, Floor 5, Number 2 Capital Quarter, Tyndall Street, CF10 4BZ

Signed: Date:[insert date here]

Print name: DR DYFED WYN HUWS
Post/Title: Director of WCISU, Health intelligence Division, Public Health Wales

For and on behalf of [insert organisation name and address here]

Signed:.....Date:.....

Print name:.....

Post/Title: .....