Public Health England

Protecting and improving the nation's health

ODR Data Request Form (v6.2)

Overview

The Office for Data Release (ODR) provides a common governance framework for responding to and approving requests to process data for direct care or secondary purposes, including research, clinical audit, service evaluation and surveillance. Data is only shared by Public Health England (PHE) for these purposes, once **ODR Approval** has been satisfied and where applicable, appropriate contractual controls are in place.

ODR Approval confirms:

- there is an explicit and specific medical purpose for processing PHE data
- the data requested are adequate, relevant and limited to what is necessary to fulfill the purpose(s)
- processing will be fair, lawful and transparent
- the applicant has appropriate organisational, technical and contractual safeguards in place, including protection against unlawful or unauthorised processing, access, loss, destruction or damage for their own organisation, or any person or organisation acting under their instruction; and
- the conduct of research meets the highest ethical standards.

Completing the ODR data request form and submitting a valid application

To start your application for ODR Approval, the ODR data request form must be completed. Details given in this form, alongside supporting documentation, will be used to review your application.

To be valid, **all applications received by the ODR must include, as a minimum:**

- the completed ODR data request form
- a clear, specific and unambiguous scientific protocol (detailing PHE as the source of data and describing how PHE data will be processed); and
- a data specification clearly identifying each variable of interest and any characteristics, codes or dates that will be used to define the population or restrict the data (inclusion/exclusion criteria).

Most applications will require more information than can be provided by these documents alone. As such, additional supporting documentation will be prompted by this form or by the ODR, depending on the type of project, the level of identifiability of the data you require, your security assurances, and whether any other person or organisation outside of your organisation is involved in the project.

It is essential that all sections of this form are completed accurately to ensure that your application can be processed efficiently. For guidance on how to complete each section of this form read the **ODR Approval Guidelines: completing the ODR data request form (Annex A)**

To support you in understanding what information to complete and supporting documentation to share with the ODR, this form uses conditional logic. This means that based on your responses, the form will highlight additional instructions or follow-up questions that are specific to your project. Read each question carefully. Most questions in the form have help text to assist you in completing them. However, if you are unsure how to respond to a question, you can arrange to speak to an ODR Data Access and Confidentiality Manager by emailing ODR@phe.gov.uk.

All fields highlighted with a red border are mandatory and must be completed for the form to be accepted.

Section A: Chief investigator, organisation information and primary point of contact

Provide details of the individual who is leading on the proposed project and has overall responsibility for its day-to-day management, outputs and dissemination of results. This individual will typically be the main point of contact for the ODR. Where the chief investigator has delegated the management of this application, stipulate the primary point of contact that will liaise with the ODR in section A3.

A1: Chief investigator

A1.1: Title	
A1.2: First name	
A1.3: Surname	
A1.4: Role / job title	
A1.5: Email address	
A1.6: Work telephone / mobile	

A2: Chief investigator's organisation

A2.1: Organisation name	
A2.2: Organisation department	
A2.3: Registered organisation address	Address Line 1
	Address Line 2
	City
	United Kingdom
	Postcode
A2.4: Organisation type	
	If other, please specify

A3: Point of contact for day-to-day correspondence about your application

If the main point of contact for this application is not the chief investigator named in A1.1, provide the full name and contact details of the person designated to serve as the primary contact for the ODR to liaise with.

A3.1: Primary contact name	Main contact name
A3.2: Primary contact email address	Main contact email

Section B: Project sponsor (research projects only)

All research carried out within the NHS or social care involving NHS patients, their tissue or data requires a research sponsor in accordance with the UK Policy Framework for Health and Social Care Research (2017). The sponsor is the individual, company, institution or organisation that takes on legal responsibility for the initiation, management and/or financing of the research.

B1.1: Tick if sponsor's name and address is the same as given in A2.1 ☐

B1.2: Sponsor's name

B1.3: Sponsor's address

Address Line 1

Address Line 2

City

Postcode | United Kingdom

Section C: Funding arrangements

The administrative, operational and technical services directly attributed to the release of PHE data for a specific project will be charged for by the ODR at full economic cost. All fixed and variable costs are described in the ODR Approval Guidelines: cost recovery.

Charges will be waived in a limited number of scenarios. Advice should be sought from the ODR to understand the scale of costs associated with your project prior to submission to ensure adequate funding arrangements are in place. Should cost recovery apply and funding not be in place, your application for ODR Approval should be deferred. Should your project have more than one funder, document in Section K (any additional information)

C1.1. Tick if the funder's name and address is the same as given in A2.1 ☐

C1.2: Name of awarding institution

C1.3: Address of awarding institution

Address Line 1

Address Line 2

City

Postcode | United Kingdom

C1.4: Reference(s) assigned the awarding institution

If you have multiple references please separate them with a comma

Section D: Project summary

The project summary provides the ODR with an overview of the project, as well as the broader anticipated impact(s) and beneficiaries of your project. If your application for PHE data is successful, the responses provided to questions D2.1-2.4 will be published in the PHE Data Release Register [hyperlink to website]. Examples of published lay summaries can be viewed by downloading the Register or in ODR Approval Guidelines: lay summary (Annex E)

Note that the summary provided in this form does not bypass the requirement for a clear, specific and unambiguous scientific protocol to accompany your application. See ODR Approval Guidelines: scientific protocol (Annex B) for recommendations on the minimum set of scientific, ethical, and administrative elements that should be addressed in the protocol.

D1: Overview

D1.1: ODR reference	Provide any references assigned to this project by the ODR. Leave blank if this request is for a new project
D1.2: Data sharing contract reference	Reference any data sharing contract held with PHE for this project. Leave blank if new project
D1.3: Project title	The project title should state clearly and concisely the proposed project. Any abbreviations should be spelled out in full.

D2: Lay summary

A project-specific lay summary is a mandatory requirement for all applications for ODR Approval. The prescribed format of the lay summary is outlined in questions D2.1-D2.4 and the responses provided must follow the editorial requirements set out in ODR Approval Guidelines: lay summary (Annex E)

D2.1: Describe in plain English a clear explanation of the overall project aim(s) and objectives (limit to 2-3 sentences)

D2.2: Describe in plain English a clear explanation of the health problem to be addressed by the project, why this project is needed and how existing evidence supports the need for this work (limit to 200-300 words)

D2.3: Describe in plain English a clear summary of the projects methods, explaining how PHE data will be processed. This should include information on (but not limited to) the type or source of data required for the study, data collection, sampling and analysis methods. Where the project involves data linkage or use of data processors, this must be described (limit to 200-300 words)

D2.4: Describe in plain English the anticipated public health benefits and/or impact of conducting this project. This should include the potential beneficiaries, how your project may impact them and how you will facilitate this (limit to 200-300 words)

D3: Project type

D3.1: Indicate if the project is research, service evaluation, clinical audit or surveillance (usual public health practice). If these broad definitions to not describe your project, select 'other' and provide an alternative description

- ☐ Research
- ☐ Service Evaluation
- ☐ Clinical Audit
- ☐ Surveillance (usual public health practice)
- ☐ Other — If other, please specify

D4: Patient and/or professional contact

D4.1: Does this project involve using PHE data to contact patients, service users and/or health care professionals?

If yes, provide details of how the data will be used and accompany your application with copies of the contact materials (such as draft letters or emails).

D5: Project timeline

Provide an indication of the project timeline. The duration should consider the complete data lifecycle, including requirements for retention and archiving, up to and including the deletion of the data.

D5.1: Estimated project start date

D5.2: Project duration (months)

D6: Research databases and access procedures

Organisations responsible for the management of research databases may apply for review of their governance arrangements and sub-licensing arrangements to enable sharing with third parties.

D6.1: Will the data requested be curated for a research database?

If yes, provide details. Where the research database proposes to share the data with third parties, accompany your application with any documentation (such standard operating procedures) that describe: (1) the data management plan for the research database, (2) the access policy and assessment process (including risk assessment) and (3) the contractual controls that will be used, including a copy of the sub-license.

Section E: Data requirements (mandatory)

The data requirements section of this form provides the ODR with an overview of the data that is directly relevant and necessary for the conduct of the project, its level of identifiability and its source. In addition to the information below, all applications must be accompanied by a detailed data specification in accordance with the criteria described in ODR Approval Guidelines: data specification (Annex C).

E1: Data specification summary

E1.1: Classification of data requested (select appropriate classification)

☐ **De-personalised:** 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 characteristics). The data will be released with controls in line with the ICO Anonymisation Code of Practice.

☑ **Personally identifiable:** the data request includes direct identifiers (eg name, address, NHS number, date of birth) 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 personally identifiable data, an extant legal gateway must be present (see Section G) and applicants must be able to demonstrate they are compliant with the right to be informed. Data will be released with controls.

E1.2: List the dataset(s) requested from PHE in this application which are necessary for the conduct of your project (for example 'Health Care Acquired Infections' or 'National Cancer Registration and Analysis Service')

E1.3: Where PHE data will be linked to other data sources, provide an outline of how the linkage will be conducted. This should include all organisations that will be involved and their respective roles in the data linkage

You must share with ODR a diagram to illustrate the proposed data flows - see Annex A for instructions.

E2: Other data processed for this project

E2.1: Will any other personally identifiable or de-personalised data, which is not controlled by PHE, also be processed for this project?

If yes, provide the dataset name, classification of the data, the legal basis for processing, and the dataset period.

Section F: Programme-level support

Access to some PHE datasets is dependent of the positive review of the scientific value, integrity and feasibility of the proposed project by a programme-specific research advisory committee (RAC) or programme lead. To understand if your project requires approval from a programme, read the ODR Approval Guidelines: completing the ODR data request form (Annex A)

F1: Programme support

F1.1: Has support been granted? If yes, provide the name of the research advisory committee (RAC) or programme lead.

If yes, please specify from which programme

F1.2: Programme-level reference

F1.3: Date of programme support

You must accompany your application with a copy of the approval letter (if provided) and any relevant correspondence from the programme.

F1.4: Identify any contacts within the programme that your request has been discussed with

Section G: Lawful basis to process personally identifiable data

G1: Legal gateway (common law duty of confidentiality)

A duty of confidentiality arises when information is obtained in circumstances where it is reasonable for a person providing information to expect that it will be held in confidence by the recipient (such as the relationship between a patient and the health professionals who care for them). This duty extends beyond death and is distinct from obligations under data protection legislation (see Section G2). However this duty is not absolute and confidential information or confidential patient information (collectively referred to as personally identifiable data in this form) may be lawfully disclosed when there are valid grounds to set this duty aside and project purpose cannot be met with either open data or de-personalised data.

If your application includes the processing of personally identifiable data, you must include evidence of how the duty of confidentiality has been set aside and demonstrate to the ODR:

- the organisation(s), including PHE, transferring personally identifiable data have a legal basis to share the data for the specific purpose(s) in the scientific protocol
- the organisation(s), including PHE, receiving the data have a legal basis to receive and process the data for the specific purpose(s) described in the scientific protocol; and
- the organisation(s) which will act upon or link personal data have a legal basis to do so.

G1.1: Direct care - authorisation from your organisation's Caldicott Guardian

To demonstrate the processing will be legal, ethical and strictly for direct care purposes, provide the name of your Caldicott Guardian and accompany your application with a signed letter that demonstrates their support for this project. A detailed description of the evidence required is set out in ODR Approval Guidelines: completing the ODR data request form (Annex A). It is recommended these guidelines are reviewed carefully to ensure this letter captures the required detail and is within the time parameters set. Note research cannot lawfully be conducted under these grounds.

Caldicott Guardian name

G1.2: Informed consent

The individual has capacity and has provided their explicit, informed consent to the processing described in this application.

Your application must be accompanied by all materials used in the consent process; this should include the consent form(s) and all associated participant information materials.

G1.3: Statutory exemption under the Health Services (Control of Patient Information) Regulations 2002

Exemption obtained for this project:

G1.4: Regulations 2, 3 & 5 (Control of Patient Information) Regulations 2002

G1.4.1 Reference:

G1.4.2 Date of next renewal:

I have attached all letters, including evidence of positive annual review, from the Secretary of State or Confidentiality Advisory Group documenting that an exemption to set aside the common law duty confidentiality has been granted and is extant. Where an exemption is in place for a contact exercise, alongside evidence of the exemption, all copies of materials (letters etc) to be used to contact individuals are also attached.

G2: Legal gateway and transparency (data protection)

The first principle of data protection (Article 5.1(a)) requires that all personal data is processed lawfully, fairly and transparently. Therefore, if you are requesting to process personally identifiable data you must have a lawful basis to do so as set out in Article 6 and Article 9 (UKGDPR). This is in addition to a common law exemption.

G2.1: Article 6 lawful basis for processing personal data

The lawful grounds for processing personal data are set out in Article 6 of the UK General Data Protection Regulation (GDPR). Select a lawful basis below

- 1(a): Consent
- 1(b): Contract
- 1(c): Compliance with a legal obligation
- 1(d): Vital interests
- 1(e): Public interest
- 1(f): Legitimate interests

G2.2: Article 9 condition for processing special category personal data

To lawfully process special category data (which includes health data), you must also identify a separate condition for processing special category data under Article 9. Select the condition(s) for processing below:

- 2(a): Explicit consent
- 2(b): Obligations/rights of the controller/data subject
- 2(c): Vital interests
- 2(d): Legitimate activities
- 2(e): Made public by the data subject
- 2(f): Legal claims
- 2(g): Substantial public interest
- 2(h): Preventative or occupational medicine
- 2(i): Public interest in the area of public health
- 2(j): Archiving purposes in the public interest, scientific or historical research purposes

G2.3: Privacy notice

Applicants requesting personally identifiable data must demonstrate that they have in place a privacy notice that informs the subjects of the processing of their personal data, with due reference to the role of PHE. Detailed guidance to support you in meeting this legal responsibility is available from the Information Commissioner's Office and summarised in ODR Approval Guidelines: completing the ODR data request form (Annex A) and privacy notice (Annex D).

Section H: Ethics approval for research

Where data is requested for the conduct of research on a population sampled because of their current or historic relationship with the NHS, you must evidence NHS REC Favorable Opinion has been obtained. For other populations, details of ethical oversight by the sponsor should be supplied.

H1.1: Research Ethics Committee (REC) name

H1.2: Reference(s) assigned by the REC

H1.3: I have attached all REC approval letter(s), including amendments

Section I: Information governance, data management and security assurances of the applicant's organisation (mandatory)

For all requests, the ODR will check that the organisation named in Section A has in place appropriate organisational and technical safeguards to process the data.

I1: Information governance management declaration

- I certify that the individual(s) who will process the data is a/are *bona fide* worker(s) at the applicant's organisation (Section A).
- I certify that the individual(s) (including permanent, temporary and locums) who 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 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.

I, the applicant, certify by ticking this box that the above organisational information governance requirements have been met

I2: Territory of processing

I2.1: Territory of processing

If other, please specify

I3: Data protection registration (UK organisations only)

The Data Protection (Charges and Information) Regulations 2018 requires every organisation that processes personal information to pay a fee to the Information Commissioner's Office (ICO), unless they are exempt. You must evidence this is satisfied.

I3.1: Data Protection Public Register registration number

I3.2: Registered organisation name

I3.3: Registration expiration date

I4: Security assurance (provide one of the following)

You must provide evidence of one of the three security assurances (identified below) to demonstrate that your organisation is practicing good data security and have in place appropriate organisational, physical and technical measures that ensure the confidentiality, integrity and availability of the data requested (including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage).

✔	Data Security and Protection Toolkit (DSP Toolkit) Organisation code		
☐	ISO 27001:2013	I have attached my organisation's certificate	
☐	SLSP	I have attached my project specific system level security policy	

Section J: Data processor(s) acting under instruction

All fields in this section are mandatory if a third party (a person, public authority, agency or other body) will act on the documented instructions of the controller to process the data and the data cannot be rendered anonymous to the ISB1523: Anonymisation Standard for Publishing Health and Social Care Data. The formal definition of the 'data processor' can be found in the UK GDPR Article 4(8). Where there are multiple processors (or a processor has instructed a sub-processor), repeat the content of Section J for all parties. This information can be included in Section K: Any additional information.

For each processor (or their respective sub-processor(s), a fully executed data processing agreement must accompany your application. The data processing agreement must comply with the obligations prescribed in Article 28 –36 of UK GDPR and terms broadly mirror controls that will be placed on the applicant by PHE. For further information, read ODR Approval Guidelines: data processors (Annex H)

J1.1: Are you engaging a data processor to process the data requested?

If yes, complete J1.2 and J1.3

J1.2: Data processor name

J1.3: Data processor address

Address Line 1

Address Line 2

City

Postcode

United Kingdom

Where there are multiple data processors (or a processor has instructed a sub-processor), repeat the content of Section J for all parties. This can be included in Section K (any additional information). You must also include share with ODR a diagram to illustrate the proposed data flows (see Annex A, E1.3).

J2: Information governance assurances - data processor declaration

When instructing the data processor, you must execute a data processing agreement (a type of contract). This contract must bind the data processor to the data controller in respect of its processing activities, as specified in this application. In addition, you must certify to the ODR that the data processor has provided you with sufficient guarantees that it will implement appropriate technical and organisational measures, and that you will continue to ensure their compliance with these measures on an ongoing basis.

- I certify that a data processing agreement has been executed that:
  - provides an explicit, written directive to the data processor to process the data for specific, time-limited purpose(s) as presented to ODR in this application; and
  - complies with and enforces the legal obligations under Articles 28 – 36 of UK GDPR.

- I certify that appropriate due diligence has been conducted to demonstrate that:
  - the processor that can provide “sufficient guarantees” (in particular,terms of its expert knowledge, resources and reliability) to implement appropriate technical and organisational measures; and
  - the data processor will conscientiously discharge their obligations, including with regards to the confidentiality of the data and their direct obligations under the UK GDPR.

- I certify that the Data Processor’s compliance will be reviewed on an ongoing basis, in order to satisfy the accountability principle.

☐ **I, the applicant, certify by ticking this box that the above responsibilities have been addressed and a copy of the executed data processing agreement accompanies this application.**

J3: Confidentiality and data protection assurance(s) - data processor

J3.1: Territory of processing ☐ If other, please specify

J3.2: Data Protection Public Register registration numner

J3.3: Registered organisation name

J3.4: Registration expiration date

J3.5: Security assurance (provide one of the following)

☐ **Data Security and Protection Toolkit (DSP Toolkit)** — **Organisation code:** **Version completed:**

☐ **ISO 27001:2013** — I have attached the data processor's ISO27001:2013 certificate

☑ **SLSP** — I have attached the data processor's project specific system level security policy

Section K: Any additional information

Stipulate any other information relevant to this project you think the ODR should be aware of.

Section L: Declaration (mandatory)

By submitting this application form to the ODR I, the chief investigator, certify:

- the information contained in this application form is true, correct and complete. I understand that any misrepresentations may invalidate my application or lead to a delay in access to data
- I have read the ODR Approval Guidelines, and where applicable, sought assistance from the ODR/ subject specific experts in the development of my application
- I have consolidated all accompanying evidence as prompted by this form and the ODR Approval Guidelines: application requirements; and
- I understand that where PHE employees make intellectual, scientific and professional contributions to this project, their input will be acknowledged through co-authorship or by recognition as non-author contributor on all publications produced from the data.

Date of declaration Save Application

Section M: Summary of evidence

- ☐ Attach scientific protocol and data specification
- ☐ Attach a data flow diagram illustrating the proposed data flows
- ☐ Attach any contact exercise materials
- ☐ Attach a copy of the approval letter and any relevant correspondence from the programme
- ☐ Attach a letter of support for the project from your Caldicott Guardian
- ☐ Attach a blank copy of the consent form(s) and all associated patient information materials (such as letters of invitation, leaflets, questionnaires)
- ☐ Attach supporting evidence of a statutory exemption to common law
- ☐ Attach a UK GDPR compliant privacy notice
- ☐ Attach REC approval materials
- ☐ Attach a copy of your ISO27001 certificate
- ☐ Attach a copy of your SLSP
- ☐ Attach a copy of your outsourced organisation's ISO27001 certificate
- ☐ Attach a copy of your outsourced organisation's SLSP