Public Health England

Protecting and improving the nation's health

ODR Data Request Form (April 2018 V5-alpha.6)

Overview

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

ODR Approval confirms that:

- there is an explicit and specific medical purpose for processing PHE data
- the data requested are the absolute minimum necessary to fulfil the purpose(s) and privacy by design is applied
- 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 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 (inclusion/exclusion criteria) that will be used to define the population or restrict the data)

Most applications 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 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.

The ODR wants to process your application for PHE data as quickly as possible. It is therefore 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 Notes for Applicants document.

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. Please 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, please arrange to speak to an ODR Data Access and Confidentiality Manager by emailing ODR@phe.gov.uk or calling 020 7654 8030.

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

Section 1: chief investigator, organisation information and primary point of contact
These are the details of the individual who is leading on the proposed project and has overall responsibility for the day-to-day management, outputs and dissemination of the project. This individual will typically be the main point of contact for the ODR.

Chief Investigator:	
Title:	Sir
First name:	Johann
Surname	Bloggs
Post:	Newspeak Administrator
Email address:	johann.bloggs@example.com
Work telephone/ mobile:	0123456789

Chief Investigator's organisation:	
Organisation name:	Ministry of Truth
Organisation department:	Records Department
Registered organisation address:	Senate House
	University of London
	London
	United Kingdom
	WC1E 7HU
Organisation type:	Government agency outside of health and adult social care
	If other, please specify

If the primary point of contact from this application is different from Chief Investigator details in Section 1, please complete this section	
Primary correspondence contact name and email address for this application:	Main contact name
	Main contact email

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

Section 2: sponsorship (where applicable)
Complete the name and address of any sponsor for this project.
All research projects that involve NHS patients, their tissue or information must have a sponsor. Details of sponsor must be provided below.

Sponsor: Tick ✔ if sponsor name and address is the same as that given in section 1	
Name of Sponsor:	
Address of Sponsor:	Address Line 1
	Address Line 2
	City
	Postcode / United Kingdom

Section 3: funding
Complete the name and address of any funder for this project.

Funder: Tick ✔ if funder name and address is the same as that given in section 1	
Name of awarding institution:	
Address of awarding institutions:	Address Line 1
	Address Line 2
	City
	Postcode / United Kingdom
Reference(s) assigned by awarding body:	awarding-body-ref-123

Section 4: project summary See guidance for more information.

Project Overview	
ODR reference:	Provide any references assigned to this project by the ODR. Leave blank if this request is for a new project
Data Sharing Contract Reference:	Reference any data sharing contract held with PHE for this project. Leave blank if new project
Project title:	My Test Import Project

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

Lay summary

Please write a clear, plain English explanation of your project, which is suitable for a non-technical audience and reviewers who may not be experts in this field. If your application for ODR Approval is successful, this summary will be used in the PHE Data Release Register. If it is felt that your plain English summary is not clear and of a good quality then you may be required to amend it as a condition of ODR Approval.

Provide a clear explanation of the overall project aim(s) and objectives:	To protect and improve the nation's health and wellbeing, and reduce health inequalities.
Provide a clear explanation of the health problem to be addressed by the project, why this project is needed and how the existing body of evidence supports this work.	When we think about good health, the vast majority of us think about our NHS and the care we get through hospitals and GPs. But the NHS of itself cannot improve the health of the nation. This depends more substantially on a prosperous economy and the choices that we make as individuals and families.
Provide a clear summary of the projects methods, explaining how PHE data will be processed. As appropriate, this should include information on (but not limited to) the data required for the study, data collection, sampling and analysis methods. Where data linkage or outsourced organisations are required, please stipulate.	We do this through world-leading science, research, knowledge and intelligence, advocacy, partnerships and providing specialist public health services.
Describe in plain English the anticipated public health benefit(s) and/or impact of conducting this project:	We will improve the health of the whole population.

Summary of project type

See information here (hyperlink) for defining research and other types of projects.

- [x] Research
- [ ] Service Evaluation
- [ ] Clinical Audit
- [x] Surveillance
- [ ] Other — If other, please specify

Project timeline

Project start date:	07/11/2019
Project duration(months):	120

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

Section 5: data specification (mandatory)

Data specification:

Classification of data requested (please 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 characteristic). 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 7) and applicants must be able to demonstrate they are compliant with the right to be informed. Data will be released with controls.

Summarise the dataset(s) requested for the processing activities. A comprehensive data specification must accompany your application.

Outline any data linkage requirements between (1) PHE data that are not routinely linked, and/or (2) to data controlled by any other organisation. Provide a data flow diagram showing each of the respective parties involved in the processing of the data. Where personally identifiable data is moving between organisations, identify the data to be shared. See Notes for Applicants for more information and an example data flow diagram.

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

Data sharing	
Do you intend to onwardly share the data? If yes, please provide detail of who and under what conditions:	No
Data details	
Is data already held for this project/purpose:	No
Provide the dataset name, classification of the data, the legal basis for processing, and the dataset period.	
Patient contact	
Does this project involve patient contact (directly or indirectly through a clinical team/service provider)? If yes, please give details.	No

Section 6: PHE programme-level support

Programme support:	
Has programme support been granted?	Not applicabl / If yes, provide detail
Programme approval reference:	
Date of programme approval:	
	Please attach a copy of the approval letter and any relevant correspondence from the programme.
Please identify any contacts within PHE your request has been discussed with:	

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

Section 7: legal gateway to process personal data and special categories of personal data
(mandatory for any request for personal data as defined under Article 4 of the General Data Protection Regulation (GDPR), including name, address, postcode, date of birth, NHS number or free text)

To process personally identifiable data, an exemption to the common-law duty of confidence must be evidenced.

Legal gateway (common law)

Indicate the legal gateway under which personally 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. Please complete relevant section(s) below:

Direct care

The Caldicott Review (hyperlink) defines ódirect careô 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

Caldicott guardian name:

Please attach a signed letter from your Caldicott Guardian. This letter must be dated within three months of the application date.

Informed consent

Please attach a blank copy of the consent form(s) and all associated patient information materials (such as letters of invitation, leaflets, questionnaires)

Do you have a consent letter and any materials to attach? No

Statutory (Section 251) exemption

Which S251 exemption is required for this project: Regulation 2

Regulations 2, 3 & 5 (Control of Patient Information) Regulations 2002

S251 reference: s251-ref-234 Date of next renewal: 07/11/2020

Do you have any S251 supporting materials to attach? No

Please attach all letters documenting that Section 251 support has been granted and remains extant, sent to you by the Health Research Authority or Public Health England for this project. Where an exemption is in place for a contact exercise, attach all copies of patient, public or health service facing materials to be used.

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

Legal gateway (data protection):

The General Data Protection Regulation (GDPR) requires that in order for processing of personal data to be lawful, the data must be processed on a legitimate, lawful basis. There are the 6 lawful bases for processing personal data under GDPR. At least one of these must apply whenever you process personal data

Article 6 lawful basis for processing personal data:

- ☐ 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

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

Article 9 condition for processing special category personal data:

- ☐ 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

Applicants requesting personal data must also demonstrate that they have in place a privacy notice that informs the subjects of the data about the collection and use of their personal data, with due reference to the role of Public Health England. Detailed guidance is available from the Information Commissioner's Office on how to create a privacy notice and what information must be included, placing an emphasis on making them easy to understand and accessible

Section 8: ethics approval for research

Where data is requested on populations due to their current or historic relationship with the NHS, evidence of ethical oversight must be presented from the Health Research Authority.

HRA Research Ethics Service approval (for research requests only):

Has ethics approval been obtained and from whom?	**REC Committee name:**
	REC reference number
	Please attach a copy of the final REC approval letter and letters documenting any REC-approved amendments
	Do you have any REC approval materials to attach? ☐

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

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.

- 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.

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

Confidentiality and data protection assurance(s):

Territory of processing:	UK	If other, please specify

Fair processing assurances (insert details of your organisation's registration with the ICO on the Data Protection Public Register *(hyperlink)*)

Registration code:	ABC123
Registered organisation name:	Ministry of Love
Registration expiration date:	07/11/2025

Security assurance (provide one of the following)

☐ **Data Security and Protection Toolkit (DSP Toolkit)**	**Organisation code:**	
☑ **ISO 27001**	Do you have a ISO27001 certificate to attach?	No
☐ **SLSP**	Do you have a SLSP to attach?	
	(Please enclose a completed system level security policy for ODR review. A template is available upon request.)	

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

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

Data Processor: identify any organisations that data processing will be outsourced to (ie any company/organisation acting on the instruction of the applicant).	
Will any other individual(s) or organisation(s) process the data requested?	No
Organisation name:	
Organisation address:	Address Line 1
	Address Line 2
	City
	Postcode / United Kingdom

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).
  A copy of the Data Processing Agreement MUST be shared with the ODR.
- I certify that the Data Processing Contract provides an explicit, written 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.

☑ **I, the applicant, certify by ticking this box that the above responsibilities have been contractually addressed with any outsourced organisation(s)**

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

Confidentiality and data protection assurance(s):		
Territory of processing:	UK	If other, please specify
Fair processing assurances (insert details of your organisation's registration with the ICO on the Data Protection Public Register *(hyperlink)*)		
Registration code:	ABC123	
Registered organisation name:	Ministry of Love	
Registration expiration date:	07/11/2025	
Security assurance (provide one of the following)		
☐ **Data Security and Protection Toolkit (DSP Toolkit)**	**Organisation code:**	
	Version completed:	
✔ **ISO 27001**	Do you have a ISO27001 certificate to attach?	No
☐ **SLSP**	Do you have a SLSP to attach?	
	(Please enclose a completed system level security policy for ODR review. A template is available upon request.)	

Section 11: any additional information

Section 12: declaration (mandatory)

By submitting this application form to the Office for Data Release (ODR) I certify that the information contained in this application form is true, correct and complete and understand that any misrepresentation may invalidate my application or lead to delay in access to data.

I understand that where PHE employees make intellectual, scientific and professional contributions for 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 completion:	07/11/2019	**Save Application**

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Attach documents to be used in any contact exercise

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

Attachment Checklist

The following documents will be required given your responses in the application:

- [x] Attach project protocol (mandatory)
- [ ] Attach a data flow diagram illustrating the proposed data flows (see page 4)
- [ ] Attach any patient contact exercise materials (see page 5)
- [ ] Attach a copy of the approval letter and any relevant correspondence from the programme (see page5)
- [x] Attach Caldicott guardian letter (see page 5)
- [ ] Attach a blank copy of the consent form(s) and all associated patient information materials (such as letters of invitation, leaflets, questionnaires) (see page 6)
- [ ] Attach supporting evidence of a statutory exemption to common law (S251 materials (see page 6)
- [ ] Attach Regulation 3 supporting materials (see page 6)
- [x] Attach Privacy notice (see page 7)
- [ ] Attach REC approval materials (see page 7)
- [ ] Attach a copy of your ISO27001 certificate (see page 8)
- [ ] Attach a copy of your SLSP (see page 8)
- [ ] Attach a copy of your outsourced organisation's ISO27001 certificate (see page 10)
- [ ] Attach a copy of your outsourced organisation's SLSP (see page 10)

Once completed this form should be saved and sent in an email, as an attachment, to ODR. Any documents above that show a tick on completion should also be submitted to ODR as attachments on the email with this form.

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

What happens next

Once the ODR has received your application you will receive a confirmation email. This email will include a unique reference, which must be quoted in all correspondence with the ODR about your application. Your application will also be assigned a Data Access and Confidentiality Manager, who will manage the progress of your application through ODR Approval.

Please note the receipt from the ODR does not constitute the formal acceptance of your application.

Once the ODR has received your application, the information shared with ODR will be validated within normal workflow processes and timescales. If the ODR needs more information or has any queries we will contact the person named in this form as the primary contract for this project. For further information on the progress of your application please contact your assigned Data Access and Confidentiality Manager quoting your reference.