UKHSA Data Application Amendment Form

**Use this form if you are requesting to amend an approved data application.**

Should you wish to make an amendment to an approved project using protected data, you will need to submit an amendment request to UKHSA for consideration. All changes to approved applications must have UKHSA approval prior to implementation, except where it is necessary to eliminate immediate hazards to data subjects or there are minor administrative changes (such as correction of spelling, grammar or typographical errors) to approved documents.

|  |
| --- |
| Types of modifications to your approved project requiring UKHSA approval:   * to add, remove or modify the approved applicant(s), sponsor or funder * to modify the applicant(s) organisational and technical assurances (ICO fee payers registration; Data Security and Protection Toolkit ODS code or standard; ISO 27001:2013 certificate) * to amend the level of identifiability of the data * to add, remove or modify the lawful basis for processing the data (common law duty of confidentiality exemption and/or UK GDPR). This includes any substantial changes to consent materials or transparency notices * to add, remove or modify any data processor, their organisational and technical assurance (Data Security and Protection Toolkit ODS code or standard; ISO 27001:2013 certificate) or the scope of the written instruction provided to the data processor * to add, remove or modify the data specification; this include requesting further extractions of data, modifying the population or sample of interest, removing redundant variables, adding new data sources and/or seeking permission for any data linkages (including where the data is to be obtained from another data controller) * to amend the contract term (a contract extension or to reduce the term length) |

Where amendments involve modifications to approved project documents listed in your Data Sharing Contract and/or introduce additional application requirements, you must ensure all relevant mandatory and qualified evidence accompanies your amendment request. Where changes to existing documents are made you must also ensure:

* all changes are clearly identified (for example bolded or strikethrough text or tracked changes)
* all revised documents must include a new version number and be dated

Completing the amendment form

This form is available in word. UKHSA does not accept handwritten submissions.

Before completing the form, you are asked to:

* revisit the prevailing Approval Standards to understand how any proposed amendments may alter the evidence you must share with UKHSA
* familiarise yourself with associated guidelines for submitting an amendment
* ensure that you have appropriate funding in place for any amendments where cost recovery will be applied

When completing the form, ensure you do the following:

* clearly explain what the amendment is you wish to make, and the justification for making the change
* be concise and transparent about the proposed changes
* accompany your application with any modified or new evidence
* insert details of any ethical issues raised by the proposed amendments

Submitting your amendment

Amendment requests must be submitted electronically to [odr@phe.gov.uk](mailto:odr@phe.gov.uk). It is advised that all evidence is consolidated in a single zip folder, with each document appropriately labelled.

Processing your data

UKHSA will use the personal information you provide in this form and any supporting evidence to consider your application. See [further information](https://www.gov.uk/guidance/processing-your-personal-data-for-secondary-purposes) on how we collect, hold, and process your information.

Section A: Project details

A1: Project lead/Principal investigator details

|  |  |
| --- | --- |
| A1.1: Application reference (the reference used to communicate with you about your application) |  |
| A1.2: Contract reference (the reference included in the first page of your contract) |  |
| A1.3: Project title (as indicated in D1.2 of the UKHSA Data Application Form) | |
|  | |

Section B: Primary applicant

B1: Project lead/Principal investigator details

|  |  |
| --- | --- |
| B1.1: Title |  |
| B1.2: First name |  |
| B1.3: Surname |  |
| B1.4: Email address |  |
| B1.5: Work telephone / mobile |  |

B2: Organisational and technical safeguard to process the data

Demonstrate that your organisation continues to comply with its responsibility under the Data Protection (Charges and Information) Regulations 2018 to share specified information and pay a fee to the Information Commissioner’s Office (ICO). Where not applicable or exempt, leave blank.

|  |  |
| --- | --- |
| B2.1: ICO Fee Payers Registration Number |  |
| B2.2: Registered organisation name |  |
| B2.3: Registration expiration date |  |

Demonstrate that your organisation continues to have in place appropriate organisational, physical, and technical measures that protect the availability, usability, consistency, integrity, and security of the data requested.

UKHSA accepts two types of security assurance as evidence:

• a valid Data Security and Protection Toolkit to ‘Standard Met’ or ‘Standard Exceeded’

• a current ISO 27001:2013 certificate issued by an UKAS accredited certification body

B2.4: Organisation and technical assurance (select one of the following)

|  |  |
| --- | --- |
|  | Data Security and Protection Toolkit. If selected complete questions B2.5a-c |
|  | ISO27001:2013 certificate. If selected complete questions B2.6a-c |

|  |  |
| --- | --- |
| **B2.5: Data Security and Protection Toolkit** | **B2.6: ISO 27001:2013 certification** |
| B2.5a: ODS code  Click or tap here to enter text. | B2.6a: Certificate number  Click or tap here to enter text. |
| B2.5b: Latest standard attained  Click or tap here to enter text. | B2.6b: Initial registration date  Click or tap here to enter text. |
| B2.5c: Version assessed against  Click or tap here to enter text. | B2.6c: Current expiry date  Click or tap here to enter text. |

Section C: Project change(s) required

C1.1: Explain what modifications are being proposed at this time, and why the modifications are necessary. Explain their effect, if any, on the risks and benefits to data subjects

|  |  |  |
| --- | --- | --- |
| **Amendment #** | **Briefly summarise the changes to the project in lay terms. Where the change has been applied to an approved project document, note the document name, page and section number or title where the changes have occurred.**  **Each amendment should be framed ‘To add’ ‘To remove’ ‘To amend’ as applicable.** | **Explain the reasons for the change(s) and their implications for the project.**  **If the amendment substantially changes the design, methodology or may otherwise affect the value of the project, please indicate what impact the change will have.** |
| Example | To add ‘IMD 2019 (excluding Health Deprivation & Disability domain)’ to Table 1, approved data specification (Conditional approval letter, page 3). | To support our understanding of the representativeness of our sample we request IMD 2019 for all cases. We will conduct a chi-square test to examine the differences between this distribution of deprivation in the sample compared to open data published on gov.uk about the general population (denominator population). We will examine if IMD quintiles are distributed identically to the general dataset.  We have indicated that we would look at patient level factors in the protocol (aim 2), including deprivation. This is in line with the ethical assessment provided by our institutional REC. |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |
| 6 |  |  |

C1.2: Indicate any ethical issues arising from the proposed changes

|  |
| --- |
|  |

Section D: Any additional information

D1.1: Provide any other relevant information you wish to add in support of your amendment

|  |
| --- |
|  |

Section E: Supporting documents

For an amendment request to be valid for review, you must consolidate and submit as a single entity all relevant mandatory and qualified evidence. It is advised that all evidence is consolidated in a single zip folder, with each document appropriately labelled.

For each document to be shared, identify the document name and its version using the table provided.

|  |  |  |
| --- | --- | --- |
| **Document name** | **Version** | **Is the document new or modified? Where modified, identify the document previously submitted to UKHSA that should be superseded** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

Declaration

By completing this amendment form and providing the date below, I certify:

* the information contained in this amendment form is true, correct, and complete. I understand that any misrepresentations may invalidate my application or lead to a delay in access to data
* where my project involves co-applicants, each co-applicant has considered the scope of the amendment(s)
* I have read the prevailing Approval Standards and Guidelines, and where applicable, sought assistance from the subject specific experts in the development of the proposed amendment(s)
* I have read the prevailing Approval Standards and Guidelines, and have consolidated all accompanying evidence necessary for UKHSA to consider the proposed amendment(s)

|  |  |
| --- | --- |
| Signed |  |
| Name |  |
| Date |  |