**NHSE RIDAC Data Application Form**

**Use this form if you are making a new application to access protected NHS England Screening data.**

NHS England generates, curates, and integrates high quality data. Access to this data can be acquired subject to a favourable outcome from the RIDAC and the approval of a data application.

All applications are rigorously reviewed using an objective, standards-based governance assessment to ensure:

1. all processing will be fair, lawful, and transparent.
2. all processing will be for a specific, explicit, and legitimate purpose(s) and the data will not be processed in a manner that is incompatible with those purposes.

1. such purpose(s) for processing the data provides direct and tangible benefits to individuals or the health system and is expected to deliver a positive social outcome.
2. the data requested are necessary and proportionate to fulfilling the purpose(s).
3. all processing will be conducted within safe settings to protect the data from unlawful or unauthorised processing, access, loss, destruction, or damage; and
4. compliance with good standards of ethical and research integrity, including public involvement, FAIR data, and Open Science principles.

# **Completing the RIDAC Data Application Form**

The NHSE RIDAC data application form has been modified to work in line with the RIDAC Screening Research office ways of working, research workflow process and standard operating procedure.

The form has been designed to ensure that the content is personalised to the circumstances of your project.

**Before completing the form, you are asked to:**

* familiarise yourself with the Approval Standards.
* RIDAC Screening Research office work in line with the approval standards from UK Health Security Agency (UKHSA), these standards can be found using this link: <https://www.gov.uk/government/publications/accessing-ukhsa-protected-data/approval-standards>
* complete Step 1, by responding the questions on page 3.

# **Submitting your application**

The requirements for submitting a valid application are set out in the Approval Standards and Guidelines. (***Please refer to the approval standards link above***)

Please complete all relevant fields in the application form and provide all required supporting evidence.

Valid applications **must** be submitted electronically to: england.screening.research@nhs.net

It is advised that all evidence is consolidated in a single zip folder, with each document appropriately labelled.

RIDAC Screening Research office will only use the information provided in your application to determine the acceptability and feasibility of your data request. Therefore, you must demonstrate all relevant and prevailing Approval Standards have been met within the application.

Incomplete applications and missing evidence will delay the approval process.

Should your request be rejected, you may amend and resubmit your application.

# **Processing your data**

RIDAC Screening Research office will use the personal information you provide in this form and any supporting evidence to consider your application.

**Step 1. Filter questions**

# **1: Project type**

**Indicate the type of project you intend to conduct by ticking the relevant box. Select one only.**

If one of these broad definitions does not describe your project, select 'other' and provide an alternative description.

[ ]  Research

[ ]  Service Evaluation

[ ]  Clinical Audit

[ ]  Service Improvement

[ ]  Surveillance

[ ]  Other

# **2: Project type**

**Select the level of identifiability of the data you are requesting access to.**

In circumstance where the application includes the need for both de-personalised and personally identifiable data select, 'Personally identifiable'.

|  |  |
| --- | --- |
|[ ]  De-personalised  |[ ]  Personally identifiable  |

**3. Prior engagement with NHSE RIDAC**

Do you have any contacts in RIDAC or the Screening Research office with whom you have discussed the value or feasibility of this project? If so, provide details.

**Step 2: Application form**

# **Section A: Primary applicant**

## **A1: Project Lead/Chief Investigator details**

Provide details of the individual who is leading on the 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 any formal correspondence.

Where the management of this application has been delegated, stipulate the primary point of contact in section A3.

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: Applicant organisation**

Provide the identity and contact details of the substantive organisation of the Project Lead.

Include the registered address or if different, the business address or any formal correspondence, including contracts, should be addressed.

A2.1: Organisation name:

A2.2: Organisation department:

A2.3: Registered address:

A2.4: Organisation type:

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

Provide the name and contact details of the person designated to serve as the primary contact for this application.

Leave blank if this if the person identified in A1.

A3.1: Primary contact name:

A3.2: Primary contact email address:

## **A4: Organisational and technical safeguard to process the data.**

Unless exempt, demonstrate that your organisation has complied 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).

A4.1: Indicate if the Organisation named in A2.1 is exempt under the Data Protection (Charges and Information) Regulations 2018

A4.2: ICO Fee Payers Registration Number:

A4.3: Registered organisation name:

A4.4: Registration expiration date:

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

RIDAC Screening Research office 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.

A4.5: Organisational and technical assurance (provide one of the following)

[ ]  Data Security and Protection Toolkit. If selected complete questions A4.6a-c

[ ]  ISO27001:2013 certificate. If selected complete questions A4.7a-c

|  |  |
| --- | --- |
| **DSP toolkit**  |  **ISO 27001:2013 certification**  |
| A4.6a: ODS code  | A4.7a: Certificate number  |
| A4.6b: Latest standard attained  | A4.7b: Initial registration date  |
| A4.6c: Version assessed against  |  A4.7c: Current expiry date  |

A4.8: Territory of processing of Primary Applicant, where other describe.

[ ]  UK

[ ]  EEA

[ ]  Other

# **Section B: Co-applicant(s)**

In circumstances where there is a clear and documented agreement between the respective applicants to act as joint data controllers, RIDAC Screening Research office supports collaborative applications, from two or more organisations that intend to operate joint working practices in the management and delivery of the project.

Should the application be favourably reviewed, each named co-applicant will be jointly responsible for the processing controlled within the Data Sharing Contract.

It is expected that the Sponsor ensures that there are appropriate policies to effectively govern the activities of the joint working.

B1.1. Is this application is being made by two or more co-applicants? [ ]  Yes [ ]  No

The contribution of co-applicants should be acknowledged in the 'Co-applicant' form found in Appendix 1.

This form records comparable information on each co-applicant to the information recorded on the primary applicant in section A.

This form should be repeated for each additional co-applicant and included with the application.

# **Section C: Project sponsor and funding**

## **C1: Sponsor**

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.

Should the application be favourably reviewed, a data sharing contract will be executed with the Sponsor.

Provide details of the Sponsor.

C1.1: Tick if sponsor's name and address is the same as given in A2.1 [ ]

C1.2: Sponsor's name:

C1.3: Sponsor's address:

## **C2: Funding arrangements**

Services attributable to the release of the data for a specific project may be charged.

Adequate funding must be in place before an application is submitted.

Should your project have more than one funder, document in section I: 'Additional Information.'

C2.1. Tick if the funder's name and address is the same as given in A2.1 [ ]

C2.2: Funder name:

C2.3: Funder address:

C2.4: Reference(s) assigned by the funder:

 (If you have multiple references, please separate them with a comma)

# **Section D: Project**

Provide an overview of the conduct of the project, as well as the broader anticipated impact(s) and beneficiaries of your project.

Should your application be successful, the responses provided to questions D2 (lay summary) will be published alongside high-level details of your organisation and the data requested in a data uses register to support transparency around the uses of NHSE data.

## **D1: Overview**

##

D1.1: Project ID/ reference(s)

D1.2: Project title:

## **D2: Lay summary**

A project-specific lay summary is a mandatory requirement for all applications for RIDAC Screening Research office Approval.

Provide a description of the project in plain English (using non-technical language and avoiding jargon, unexplained acronyms and/or abbreviations).

All editorial requirements set out in the Approval Standards and Guidelines.

In addition to the lay summary, all applications must be accompanied by a detailed scientific protocol.

See the Approval Standards and Guidelines for further information on protocol requirements.

D2.1.1: Describe the overall aim(s) of the project.

D2.1.2: Describe the objectives of the project.

D2.2: Explain the rationale for why this project is needed, including citing evidence which supports the need for this work.

D2.3: Explain the methods you will use in your project, such as how you will obtain the data, how you will analyse it and how you will draw conclusions.

 Where the project involves data linkage, the instruction of data processors, profiling and/or automated decision making, this must be described.

D2.4: Describe the anticipated benefit(s) and/or impact(s) of conducting this project to public health or the public good; including all direct/indirect beneficiaries.

D2.5: Specify any intended outputs that will communicate the findings from this project with the beneficiaries identified in D2.4 or other relevant audiences. If you are not intending to publish your outputs, the RIDAC Screening Research office may ask you to explain why.

 [ ]  Peer reviewed scientific journals [ ]  Internal report (publication not intended)

[ ]  Conference presentation [ ]  Website

[ ]  Submission to regulatory authority [ ]  Press release

[ ]  Software products/web tools [ ]  Other

 (Open access or restricted)

Where 'other' provide further details of intended outputs below:

D2.6: Provide the URL of any websites that will highlight the conduct of the project or the outputs listed in D2.5. If the project does not operate a website, leave blank.

## **D2.7: Programme-level support**

## Access to the NHSE datasets is dependent of the positive review of the scientific value, integrity and feasibility of the proposed project by a screening programme specific Research Innovation and Development Advisory Committee (RIDAC).

D2.7.1: **Programme support**

Has support been granted?

If yes, provide the name of the Research Innovation and Development Advisory Committee (RIDAC).

D2.7.2: RIDAC ID/reference:

D2.7.3: Date of programme support:

D2.7.4: Identify any contacts within the screening programme that your request has been discussed with

## **D3: Patient and/or professional contact**

Provide details of any instance where:

1. NHSE screening programme data will be linked to
2. Any data NHSE screening data will be linked to;
3. or will be used to contact the data subject or a public health/health professional about the

data subject.

Where a contact exercise will be delivered, you must share all copies of materials that will be used to contact individuals (such as draft letters, emails, or phone scripts).

D3.1: Will this project process NHSE screening data to contact members of the public, patients, health care professionals or service users? Yes [ ]  No[ ]

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).

## **D4: Data management and information systems**

D4.1: Provide a technical description of how the data will be processed through its lifecycle, up to and including destruction.

This must include a description of any the systems, processes and other business operations that will be used when the data is in transit, is stored (including persistent storage) or destroyed.

You must also clearly document any transfers of data between co-applicants and/or data processors acting under instruction.

In addition to the technical summary, all applications must be accompanied by a logical data flow diagram to visualise the information flows within the proposed systems, any processes and interaction points between any external and internal parties.

See the Approval Standards and Guidelines for further information. <https://www.gov.uk/government/publications/accessing-ukhsa-protected-data/approval-standards>

## **D5: Project timeline**

Provide details of an indicated project timeline.

You are advised to take into account the complete data lifecycle, including requirements for retention and archiving, up to and including the deletion of the data.

D5.1: Start date:

D5.1.2 : End Date:

D5.3: Project duration (months):

# **Section E: Summary of screening data requirements**

Provide an overview of the data that is necessary and proportionate for the conduct of the project.

In addition to the information below, it is a mandatory requirement that all applications must be accompanied by a detailed data specification.

See the Approval Standards for further information. <https://www.gov.uk/government/publications/accessing-ukhsa-protected-data/approval-standards>

## **E1: Data specification summary**

E1.1 Level of identifiability

|  |  |
| --- | --- |
| [ ]  | **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 (e.g., ethnicity, sex, month and year of birth, admission dates, geographies, or other personal characteristics).  |
|[ ]  **Personally identifiable**: the data request includes direct identifiers (e.g., name, address, NHS number, date of birth), free text or is coded (pseudonymised), but would be directly identifiable in the hands of the data recipient (such a cipher that links the study specific number or code back to the real-world identifiers, like a medical record number for a hospital). To process personally identifiable data, the applicant(s) must demonstrate processing would be lawful, fair, and transparent.  |

E1.2: What NHSE screening programme dataset(s) and coverage period(s) do you require

access to?

E1.3: What screening data items/fields do you require?

Provide us with an accompanying file such as an excel document that lists the variables you require and a justification for each variable.

E1.4: State whether your project requires an extract once or whether it relies on periodic updates of the extract.

Where the project requires periodic updates, provide details of the frequency needed and why this is necessary to fulfil the Purpose(s).

If the RIDAC Screening Research office is satisfied with your reasons for updates of data, we may not require you to re-apply each time, however we reserve the right to ask you to do so.

The feasibility of the proposed periodic updates must be agreed with the NHSE system/asset owner prior to submission of the application.

## **E2: Other data processed for this project.**

E2.1: Will any other personally identifiable or de-personalised data not controlled by NHSE be processed for this project? [ ]  Yes [ ]  No

If yes, provide the dataset name, level of identifiability of the data, the legal basis for processing (where applicable), and the data controller.

# **Section F: Integrity and accountability**

All projects must be conducted within an ethical framework.

Provide details of any material ethical issues that that may arise in the conduct of the project or from its outputs.

Identify how such issues will be mitigated to ensure high standards of ethical practice are upheld throughout the project life course. This should include issues arising from but not limited to:

* managing any adverse effect on the data subject’s personal, social, or economic well-being, including how the project will safeguard the rights, safety, dignity and well-being of the data subject.
* managing departures from usual care or introducing variation between groups of individuals
* managing diminished and/or Gillick competency
* data management practices to prevent breaches to confidentiality.
* data management practices to uphold privacy and compliance with data protection.
* ensuring that the project yields appropriate results through its design, and the valid and reliable assessment of findings.
* ensuring that all findings are transparent and accessible, so knowledge is shared and developed/
* real or perceived conflicts of interest that could compromise the project, including commercial interests and restrictions on the freedom of the Applicant(s).
* All commercial interests in the delivery of the project must be declared.

F1.1: Describe any material ethical issues and mitigations that will be deployed, which have been identified in the design or conduct of the project, including pertaining to any planned outputs.

F1.2: Has the project been discussed or are there plans to discuss the project with those likely to be involved, including potential participants or those who may represent their views? If so, describe who and in what circumstance?

## **F2: Independent Ethical oversight**

Where personally identifiable data is requested for the conduct of research on a population sampled because of their current or historic relationship with the NHS, applicants must evidence NHS REC Favourable Opinion has been obtained.

For other populations, details of ethical oversight by the Sponsor should be supplied.

Where the data requested is de-personalised, you are asked to evidence the Sponsor has reviewed the application and appropriately considered all ethical implications.

F2.1: Type(s) of ethical approval obtained:

F2.2: Ethics committee name:

F2.3: Ethics committee reference(s):

## **F3: Research databases and access procedures**

Organisations responsible for the management of research databases may apply for review of their governance and sub-licensing arrangements to enable the sub-licensing of NHSE programme screening data to third parties.

For such arrangements to be considered, applicants must accompany their application with evidence that describes:

(1) the data management plan for the research database,

(2) the access policy and assessment process (including risk assessment),

(3) the contractual controls that will be used, including a copy of the sub-licence

(4) how they intend to demonstrate the uses of the data to the public (such as a data uses

 register).

F3.1: Will the screening data requested be curated for a research database? [ ]  Yes [ ]  No

F3.2: Describe the proposed management of the research database.

# **Section G: Lawful processing**

## **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.

However, Common law duty of confidence 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.

Common law duty of confidence can be set aside (without breaching confidentiality obligations) in following circumstances:

* where the individual to whom the information relates has given consent.
* where disclosure is in the overriding public interest.
* where there is a legal duty to do so, for example a court order; and
* where there is a statutory basis that permits disclosure, such as, approval under section

251 of the NHS Act 2006 or GDPR

To be protected by the law of confidential information, information must be:

(1) confidential in nature, meaning that it must have the "necessary quality of confidence“. and (2) disclosed in circumstances importing an obligation of confidence.

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 NHSE:

* the organisation(s), including NHSE, 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 NHSE, 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: Provide the applicable exemption or legal gateway to the common law duty of confidentiality.

Provide further details if more than one exemption applies:

If applicable, please include within your application supporting evidence.

|  |
| --- |
| **Direct care (If applicable)** |
| A Caldicott Guardian is a senior person within an NHS organisation responsible for protecting the confidentiality and enabling appropriate sharing of confidential patient information. Caldicott Guardians play a key role in ensuring that NHS, councils with social services responsibilities and partner organisations follow the Caldicott Principles for handling confidential patient information.<https://www.gov.uk/government/publications/the-caldicott-principles>   |
| To demonstrate processing will be legal, ethical, and strictly for direct care purposes, provide the name of your organisation's Caldicott Guardian and accompany your application with a signed letter that demonstrates their support for this project. The letter must be in line with the Approval Standards and the time parameters set. G1.2: Caldicott Guardian name: G1.3: I understand I must accompany my application with evidence of Caldicott Guardian approval for a direct care activity that involves the processing of data on my patients.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Explicit informed consent (If applicable)** |
| Where the individual has capacity and has provided their explicit, informed consent to the processing described in this application, you must accompany your application with blank copies of the consent form (including version history) and any participant information sheets. G1.4: I understand I must accompany my application with evidence of explicit informed consent. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Statutory exemption (If applicable) in relation to Regulation 2, 3 or 5, Health Services (Control of Patient Information)**  |
| Regulation 2 – Medical purposes related to the diagnosis or treatment of neoplasia (Cancer)Regulation 3 – Communicable disease and other risks to public healthRegulation 5 - General, as authorised by the Health and Research Authority (so-called s251 CAG approval), for research and non-research purpose.Where support is granted under these Regulations, it is permissive. |
| G1.5: Provide the statutory exemption applicable to the processing of personally identifiable data for this project. |
| G1.6: Describe the processing operations in scope of exemption, including but not limited to the affected population, purpose, restrictions, and retention of the data.   |

## **Regulation 2, 3 or 5, Health Services (Control of Patient Information) Regulations**

Section 251 of NHS Act 2006 gives the Secretary of State for Health the authority to make regulations that set aside legal obligations of confidentiality. These powers are exercised through the Health Service (Control of Patient Information) Regulations 2002.

Under these Regulations, support can be granted for a range of activities, for example anonymising information, accessing records to contact people for the purposes of gaining consent for research, geographical analysis, linkage, validation and clinical audit.

The key purpose of CAG is to protect and promote the interests of patients and the public, while at the same time facilitating appropriate use of confidential patient information for purposes beyond direct patient care.

Where Regulation 2, 3 or 5, Health Services (Control of Patient Information) Regulations 2002 (“Section 251”), is selected as a 'statutory exemption', you must also provide details of the approval granted by the Secretary of State or Confidentiality Advisory Group (CAG).

[Confidentiality Advisory Group - Health Research Authority (hra.nhs.uk)](https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/)

National Data Opt Out must be considered.

Your application must be accompanied by 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.

G1.6: CAG reference:

G1.7: Date of next renewal:

# **G2: Legal gateway (Data protection)**

|  |
| --- |
| If you are requesting to process **personally identifiable data (PID)**, you must demonstrate the applicant(s) has a lawful basis to do under Article 6 and Article 9 (UK GDPR). This is in addition to a common law exemption. The [ICO webtool](https://ico.org.uk/for-organisations/resources-and-support/lawful-basis-interactive-guidance-tool/) might help you determine which condition is right for your project |
|  |

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

[ ]  1(a): Consent [ ]  1(d): Vital interests

[ ]  1(b): Contract [ ] 1(e): Public task

[ ] 1(c): Compliance with a legal obligation [ ] 1(f): Legitimate interests

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

[ ]  2(a): Explicit consent [ ]  2(f): Legal claims

[ ]  2(b): Obligations/rights of the controller [ ]  2(g): Substantial public interest

 /data subject

[ ]  2(c): Vital interests [ ]  2(h): Preventative or occupational medicine

[ ]  2(d): Legitimate activities with safeguards [ ]  2(i): Public interest in the area of Public Health

[ ]  22(e): Made public by the data subject [ ]  2(j): Public interest, scientific or historical research

G2.3: Provide justification for the selection of the lawful basis and condition(s) in questions G2.1 and G2.2, drawing on any evidence material to the decision making (such as a legitimate interest test or the relevant task, function or power which is clearly set out in law).

# **G3: Transparency**

In addition to demonstrating lawful processing, applicants wishing to process personally identifiable data must demonstrate that they comply with transparency and accountability principles of UK GDPR.

You must include a project-specific privacy notice which adheres to the Approval Standards and clearly articulates the role of NHSE as a source of data, or as responsible for any other processing operations.

Review the requirement for project specific privacy notice. You may find the Information Commissioner’s office (ICO) checklist useful by using this link: [privacy-notice-checklist.pdf (ico.org.uk)](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fico.org.uk%2Fmedia%2Ffor-organisations%2Fdocuments%2F1625126%2Fprivacy-notice-checklist.pdf&data=05%7C01%7Ccarlene.parchment%40nhs.net%7C7764cfb7cfdc42b60dcb08db40edd447%7C37c354b285b047f5b22207b48d774ee3%7C0%7C0%7C638175162429729528%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=StMhRbCvHpU1lTuYz5sHsu8pZmz%2B1gIp4NJluSEVDik%3D&reserved=0)

G3.1: Describe how the project-specific privacy notice is/will be made available to the data subject(s), including:

1. the mode(s) of communication used/to be used and where the notice will be

made available electronically,

(b) the URL of the published notice.

# **Section H: 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).

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.

You must ensure that the logical data flow diagram details any processing operations between the data controller and the processor(s) acting under instruction.

H1.1: Are you engaging one or more data processors to process the data requested?

 [ ]  Yes [ ]  No

**Data Processor 1**

H1.2: Data processor name:

H1.3: Registered address:

H1.4: State the written instruction provided by the Applicant(s) to Data Processor 1 for the processing of NHSE Screening programme data.

## **H2: Data Processing Agreement**

You must fully execute a data processing agreement (a type of contract) with each Data Processor.

This contract must bind the data processor to the data controller in respect of its processing activities, as specified in the application.

## **H3: Organisational and technical assurances of the data processor**

H3.1: ICO Fee Payers Registration Number:

H3.2: Registered organisation name:

H3.3: Registration expiration date:

## **H3.4: Organisational and technical assurance (provide one of the following)**

Demonstrate that the data processor has appropriate technical and organisational measures to protect the confidentiality, integrity and availability of the data requested (including protection against unauthorised or unlawful processing and against accidental loss, destruction, or damage).

**RIDAC Screening Research office 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.

[ ]  Data Security and Protection Toolkit (DSP Toolkit), complete G3.5a-c

[ ]  ISO 27001:2013 certification, complete G3.6a-c

|  |  |
| --- | --- |
| **DSP toolkit**  | **ISO 27001:2013 certification**  |
| H3.5a: ODS code  | H3.6a: Certificate number  |
| H3.5b: Latest standard attained  | H3.6b: Initial registration date  |
| H3.5c: Version assessed against  | H3.6c: Current expiry date  |

H3.7: Territory of processing, where other describe:

[ ]  UK

[ ]  EEA

[ ]  Other

## **H4: Other Data Processor(s)**

Where more than one data processor is to be instructed to process the data (entirely or in part), you must complete a ‘Data Processor’ form (Appendix 2) for each distinct entity.

# **Section I: Any additional information**

This section allows you the opportunity to share any other relevant information with Screening Research office in support of your application.

# **Section J: Supporting documents.**

Your application will not be complete unless all the relevant supporting evidence are submitted together.

Please ensure you submit all the relevant documents that you want NHSE to consider when assessing your application.

For each document, identify the document name and version.

|  |  |
| --- | --- |
| **Document name**  | **Version**  |
|  |  |
|  |  |
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# **Declaration**

By completing the declaration below, I, the primary applicant 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 Approval Standards and Associated Guidelines, and where applicable, sought assistance from the subject specific experts in the development of my application.
* I have consolidated all accompanying evidence as prompted by this form orthe Approval Standards and Guidelines
* I understand that any changes to this application while it is in review will require this application to be withdrawn and resubmitted.

**Signed:**

**Date:**

## **Evidence checklist**

**Mandatory requirements**

[ ]  Scientific protocol

[ ]  Data specification

[ ]  Logical data flow diagram

**Qualified requirements**

[ ]  Any contact exercise materials

[ ]  Attach a letter of support for the project from your Caldicott Guardian

[ ]  Attach a blank copy of the consent form(s) and participant information materials.

[ ]  Attach co-applicant form(s)

[ ]  Attach all supporting evidence of a statutory exemption to common law\* (if applicable)

[ ]  Attach REC approval materials.

[ ]  Attach a copy of your organisation's ISO 27001:2013 certificate.

[ ]  Attach a copy of the data processor's ISO 27001:2013 certificate .

[ ]  Attach a copy of the project-specific privacy notice.

[ ]  Attach the executed data processing agreement(s) with the data processor(s)

[ ]  Attach evidence detailing governance arrangement of proposed research database.

\*Please note, this checklist assumes that the project relies upon one common law basis to process personally identifiable data.

If the project relies on a mixed model (for example consent and a statutory exemption) contact RIDAC Screening Research office to confirm you understand all qualified requirements before submission.

**Appendix 1: Co-applicant(s)**

**Use this form to capture a co-applicant. Repeat the content of this form for each distinct co-applicant using a new document.**

|  |  |
| --- | --- |
| Primary applicant (as named in section A1 of the NHSE RIDAC Data Application Form):  |  |
| Applicant organisation (as named in section A2 of the NHSE RIDAC Data Application Form):  |  |
| Project ID/reference:  |
| Project title (as indicated in D1.2 of the NHSE RIDAC Data Application Form): |

**B1: Co-applicant**

RIDAC Screening Research Office will accept applications with two or more applicants in circumstances where there is a formal agreement between these organisations to act as joint sponsors. Such joint sponsors will be jointly and severally responsible for all the systems, capacity and expertise needed to execute the project and meet any requirements set out in the Approval Standards.

In the event, an application is favourably reviewed each joint sponsor will become a party to a Data Sharing Contract. Therefore, it is important that before entering into such arrangements each applicant must fully understand the allocation of roles and responsibilities.

For each additional applicant, you must complete this Co-applicant form supplementary only to the NHSE RIDAC Data Application Form.

Each form should be labelled clearly.

B1.1: Title:

B1.2: First name:

B1.3: Surname:

B1.4: Role / job title:

B1.5: Email address:

B1.6: Work telephone/ mobile:

**B2: Co-applicant organisation**

B2.1: Organisation name:

B2.3: Organisation address:

B2.4: Organisation type:

B3: Organisational and technical safeguards to process the data

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.

B3.1: ICO Fee Payers Register registration number:

B3.2: Registered organisation name:

B3.3: Registration expiration date:

Your organisation must practice 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).

RIDAC Screening Research office accepts two types of 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. You must provide the primary applicant with a copy of the certificate for inclusion in the application.

B3.4: Security assurance (provide one of the following)

[ ]  Data Security and Protection Toolkit. If selected complete questions A3.5a-c

[ ]  ISO27001:2013 certificate. If selected complete questions A3.6a-c

|  |  |
| --- | --- |
| **Data Security and Protection Toolkit**  | **ISO 27001:2013 certification**  |
| B3.5a ODS code  | B3.6a: Certificate number  |
| B3.5b: Latest standard attained  | B3.6b: Initial registration date  |
| B3.5c: Version assessed against  | B3.6c: Current expiry date  |

B3.7: Territory of processing of primary applicant, where other describe.

 [ ]  UK

 [ ]  EEA

 [ ]  If Other, please specify:

**Declaration**

By completing this form and providing the date below, I, the co-applicant, 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 Approval Standards and Guidelines, and where applicable, sought

 assistance from the subject specific experts in the development of my application

* where one or more co-applicants are included in the application each co-applicant

is a joint sponsor to this project and it will be jointly and severally responsible for the project, including meeting any requirements set out in the Approval Standards and Guidelines

* where one or more co-applicants are included in the application, each co-applicant

will be a party to the data sharing contract executed by NHSE should the data application be favourably reviewed.

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

Processing your data

NHSE RIDAC Screening Research office will use the personal information you provide in this form and any supporting evidence to consider your application.

**Appendix 2:**

**Additional data processor(s)**

**Use this form if your project involves additional data processors to the processor named in section H.**

**Repeat the content of the form for each distinct entity that will operate as a data processor under written instruction.**

|  |  |
| --- | --- |
| Primary applicant (as named in section A1 of the NHSE RIDAC Data Application Form):  |  |
| Applicant organisation (as named in section A2 of the NHSE RIDAC Data Application Form):  |  |
| Project ID/reference: |
| Project title (as indicated in D1.2 of the NHSE RIDAC Data Application Form):  |
|  |

**H4: Additional data processors**

Under UK GDPR Article 4(2) ‘processing’ is described as ‘any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction’.

Article 4(8) of UK GDPR goes on further to describe a ‘processor’ as ‘a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller’.

It is important to remember that processing the data includes any bodies which touch the data in any way as part of the project. This may include situations such as:

* cloud hosting arrangements to securely store the data
* a specialist organisation instructed to support the distribution of surveys or invitation letters to participate in a study
* third-party analysis, consultation or interpretation of data

Where there is more than one data processor (or a processor has instructed a sub-processor), you must submit this Additional data processor(s) form with your application.

The total number of Additional data processor forms will depend on the data management practices within your project and must align to the linear data flow diagram.

All applications must be accompanied by a logical data flow diagram to visualise the information flows within the proposed systems, any processes and interaction points between any external and internal parties.

Before completing this form, you are asked to familiarise yourself with the pre-application guidance, including Approval Standards.

H4.1: Data processor name

H4.2: Registered address

H4.3: State the written instruction provided by the Applicant(s) to the additional data

processor

**H5: Data processing agreement with data processor**

You must execute a data processing agreement (a type of contract) with each data processor.

This contract must bind the data processor to the data controller in respect of its processing activities, as specified in the application.

**H6: Organisational and technical safeguards of the data processor to process the data**

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.

H6.1: ICO Fee Payers Register registration number:

H6.2: Registered organisation name:

H6.3: Registration expiration date:

You must demonstrate that the data processor has appropriate technical and organisational measures to protect the confidentiality, integrity and availability of the data requested (including protection against unauthorised or unlawful processing and against accidental loss, destruction, or damage).

NHSE RIDAC accepts two types of 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. You must provide the primary applicant with a copy of the certificate for inclusion in the application

H6.4: Security assurance (provide one of the following)

[ ]  Data Security and Protection Toolkit. If selected complete questions A6.5a-c

[ ]  ISO27001:2013 certificate. If selected complete questions A6.6a-c

|  |  |
| --- | --- |
| **Data Security and Protection Toolkit**  | **ISO 27001:2013 certification**  |
| H6.5a ODS code  | B6.6a: Certificate number  |
| H6.5b: Latest standard attained  | H6.6b: Initial registration date  |
| H6.5c: Version assessed against  | H6.6c: Current expiry date  |

H6.7: Territory of processing of primary applicant, where other describe.

 [ ]  UK

 [ ]  EEA

 [ ]  If Other, please specify:

Processing your data

RIDAC Screening Research office will use the personal information you provide in this form and any supporting evidence to consider your application.

Useful Information

Approval Standard – Confidential Patient Information

<https://www.gov.uk/government/publications/accessing-ukhsa-protected-data/approval-standards-and-guidelines-confidential-patient-information>

Approval Standard Instructions – Confidential Patient Information: guidance underpinning this approval standard will be made available in 2023.

* [MRC and HRA consent and patient information sheet preparation guidance](http://www.hra-decisiontools.org.uk/consent/).
* Using information about people in health research: <https://www.ukri.org/wp-content/uploads/2021/08/MRC-0208212-Using-information-about-people-in-health-research-2018.pdf>

<https://www.gov.uk/government/publications/the-caldicott-principles>