Generic Due Diligence questionnaire

Version 1.0

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* This Due Diligence questionnaire was developed as part of the [International COVID-19 Data alliance (ICODA) initiative](https://icoda-research.org/), which supported research projects that addressed major research questions relating to COVID-19. For more information on the ICODA research projects please see our [website](https://icoda-research.org/research/driver-projects/).
* This was drafted as part of a suite of documents to facilitate HDR UK acting as a Data Controller, promoting streamlined research by permitting HDR UK to make specific data access decisions over datasets contributed to the initiative.
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* If you have any feedback on this document please email hdrglobal@hdruk.ac.uk

**Customising this Questionnaire**

Throughout the Questionnaire, we have highlighted areas which will need amending for your specific project

Typical areas that you will need to customise:

* Your Organisation name
* The Work Area your research project will be performed in and the Provider of that Work Area
* Your contact details, e.g. Email addresses
* Laws (including data protection) in your geography or jurisdiction.

**Data Contributors - Due Diligence Questionnaire on Data Sets**

**Principles**

[ORGANISATION] recognises the importance of respecting the data sharing preferences of patients and trial participants. ***This questionnaire is designed to ensure that your participation as a data contributor is in line with these principles and respects all applicable legal requirements and ethics standards.***

**Who should complete this form?**

This form should be completed by legal, data governance or management personnel within your organisation. One individual should be nominated to be the key contact person for this form in case [ORGANISATION] has any questions or requires further information. Before submission, this form must be signed by at least one person with authority to sign on behalf of your organisation and confirm the accuracy of the answers provided.

**How should this form be completed?**

The form should be completed in English and all answers must be accurate. If you are unable to respond in English, please contact the [RELEVANT TEAM] team via the email address below for further support and guidance.

**What if I have any questions?**

If you have any questions about how to complete the Due Diligence Questionnaire, please contact the [RELEVANT TEAM] team [EMAIL ADDRESS]

**How will the information we provide be used?**

[ORGANISATION] will keep this information on record for the purposes of assessing your eligibility to either transfer specific data sets to the [WORK AREA] or our partner databanks or allow your data to be accessed in a federated fashion in your environment, for risk management purposes and for demonstrating compliance with applicable legal and ethical standards.

We may share it with our staff, professional advisors, partners, auditors, regulators, and funders, as required to carry out the due diligence connected with this project or other research projects on which we are collaborating with you.

**Your confirmation**

[ ] I/We confirm that I/we have authority to submit this form on behalf of my institution\*

[ ] I/We confirm that I/we consent to the information submitted being used for the purposes stated above\*

[ ] I/We confirm that all information entered is complete and accurate to the best of my/our knowledge and belief, having made reasonable enquiries\*

Agreed on behalf of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ by

Signatory 1:

|  |  |  |  |
| --- | --- | --- | --- |
| Signature | Name | Role | Date |
|   |   |   |   |

Signatory 2 (if applicable):

|  |  |  |  |
| --- | --- | --- | --- |
| Signature | Name | Role | Date |
|   |   |   |   |

**Definitions**

In this questionnaire:

**Anonymous Data** means information in relation to which is not possible to single out or otherwise identify a specific individual from that information. This might include, for example, aggregated statistics or data showing trends about a large population.

**Data Sets** means all data that you contribute to [ORGANISATION] by: (1) transferring such data to [WORK AREA]; (2) transferring such data to our partner databanks; or (3) allowing such data to be accessed in a federated fashion in your environment.

**De-personalised Data** means information that does not directly identify an individual because identifiers such as name, address and date of birth have been removed or encrypted, but is still about an individual person who it might, in theory, be possible to re-identify, for example if the data was combined with different sources of information.

**[WORK AREA]** means a [trusted research environment (TRE)](https://ukhealthdata.org/wp-content/uploads/2020/07/200723-Alliance-Board_Paper-E_TRE-Green-Paper.pdf) within which approved researchers are able to analyse data which they have been provided access to, for a defined and approved research purpose. **[INSERT DETAILS]**

**Personally Identifiable Data** means information that identifies a specific person. Identifiers include but are not limited to: name, address, full postcode, date of birth or identification number.

**Research Purpose** [ ].

1. **Data Sets**

|  |  |  |  |
| --- | --- | --- | --- |
| **Number**  | **Question** | **Yes/No** | **Details**  |
| 1.1 | Please insert the title(s) of the Data Set(s) in the “Details” column  |  |  |
| 1.2 | Are the following types of data included in the Data Sets?(a) clinical records(b) electronic patient records(c) clinical registries(d) clinical trial records(e) health system operational data(f) digital device data (e.g. app, sensor, wearable) (g) environmental monitoring data (h) administrative and socio-economical data (i) genomics or genetic data(j) imaging data(k) geospatial data(l) government or National statistics(m) patient or public survey data(n) Other – please specify data types in the “details” column  |  |  |
| 1.3 | What is the sample size in the Data Sets? |  |  |
| 1.4 | Are the Data Sets currently publicly available and open to all researchers to use?  |  |  |
| 1.5 | If you answered “no” to question 1.4, please explain the restrictions on data access that are currently in place in the “Details” column  |  |  |
| 1.6 | Are the following types of data included in your data set:1. Personally Identifiable Data
2. De-personalised Data
3. Anonymous Data
4. Other – please specify in the “Details” column

If you answered “yes” to question 6(a) please contact [CONTACT DETAILS] discuss further. Personally Identifiable Data is not permitted in the [WORK AREA] and the data will need to be De-personalised before it can be contributed.  |  |  |
| 1.7 | Do you intend to transfer the Data Sets to the [WORK AREA]? |  |  |
| 1.8 | If you answered “no” to question 1.7, will the Data Sets be stored in a Databank and accessible via the [WORK AREA]?  |  |  |
| 1.9 | If you answered “yes” to question 1.8, please insert the name of the Databank in the “Details” column |  |  |
| 1.10 | If you answered “no” to questions 1.7 and 1.8, please explain in the Details column where the data will be stored and how it will be accessed (for example the data will not be moved from you as Data Contributor but will be accessed using federated analytics) |  |  |
| 1.11 | Are there any restrictions on publication of research outcomes from the Data Sets? |  |  |
| 1.12 | If you answered “yes” to question 1.11, please describe the restrictions in the “Details” column  |  |  |

1. **Legal basis for data use**

European data protection laws require any organisation processing personal data (including De-personalised Data) to have a valid legal basis for that processing activity, for example consent of the data subjects or a public interest. The purpose of this section of the questionnaire is to understand the legal basis on which your Data Sets can be processed for research processes.

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Question** | **Yes/No** | **Details**  |
| 2.1 | Please explain in the “Details” column the legal basis on which the Data Sets were collected |  |  |
| 2.2 | Please explain in the “Details” column the legal basis on which to **use the Data Sets for the Research Purpose**?  |  |  |
| 2.3 | Are there any restrictions on who can access the Data Sets?  |  |  |
| 2.4 | If you answered “yes” to question 2.3, please provide additional details on the restrictions that apply in the “Details” column |  |  |
| 2.5 | Are there any other specific data protection, legal or regulatory restrictions that would limit the use of the Data Sets for the Research Purpose?  |  |  |
| 2.6 | If you answered “yes” to question 2.5 please provide details in the “Details” column  |  |  |

1. **Ethical review**

To protect participants and maintain public confidence in research, it is important that all research is conducted with honesty and integrity and protects the safety and dignity of patients. In many countries the law or good practice requires that a research ethics committee approves collection and/or use of health data. This purpose of this section of the questionnaire is to understand what ethical reviews or approvals are required under the laws that apply to your organisation and whether required reviews/approvals have taken place.

|  |  |  |  |
| --- | --- | --- | --- |
| **No** | **Question** | **Yes/No** | **Details**  |
| 3.1 | Was ethical review required under applicable laws, rules, regulations or guidance for the **collection of the Data Sets**? |  |  |
| 3.2 | If you answered yes to question 3.1, was the ethical review carried out? |  |  |
| 3.3 | If you answered yes to question 3.2, who carried out the ethical review? Please insert in the “Details” column  |  |  |
| 3.4 | Did you obtain consent from the data subjects to collect their data and use the Data Sets for the Research Purposes? |  |  |
| 3.5 | Is ethical review required under applicable laws, rules, regulations or guidance for the **Research Purpose**? |  |  |
| 3.6 | If you answered yes to question 3.5, has an ethical review been carried out to date? |  |  |
| 3.7 | If you answered yes to question 3.6, who carried out the ethical review? Please insert in the “Details” column  |  |  |
| 3.8 | Are there any other ethical issues we should be aware of in relation to the Data Sets? |  |  |
| 3.9 | If you answered “yes” to question 3.8 please provide details in the “Details” column  |  |  |

1. **Public and patient review**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Question** | **Yes/No** | **Details**  |
| 4.1 | Has there been any public, patient or lay person input or representation related to the collection or use of the Data Sets? |  |  |
| 4.2 | If you answered “yes” to question 4.1, please briefly describe the process for public, patient or lay person input or representation in the “details” column  |  |  |