ICODA Data Contributors - Due Diligence Questionnaire on Data Sets

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Principles

Convened by Health Data Research UK (HDR UK), ICODA is an independent consortium of leading life science, philanthropic and research organisations uniting to respond to the COVID-19 global pandemic.

ICODA's Ethics and Governance Framework 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 ICODA 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 ICODA 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 ICODA team at Health Data Research UK: ICODA@hdruk.ac.uk

How will the information we provide be used?

HDR UK will keep this information on record for the purposes of assessing your eligibility to either transfer specific data sets to the ICODA Workbench 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 ICODA by: (1) transferring such data to the ICODA Workbench; (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.

ICODA Workbench means a trusted research environment (TRE) within which approved researchers are able to analyse data which they have been provided access to, for a defined and approved research purpose.

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 means any form of scientific research into COVID-19 or any other future pandemic, significant outbreak of disease or other global health initiative or health challenge, including but not limited to research into transmission, symptoms, treatments and vaccinations.

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: (a) Personally Identifiable Data (b) De-personalised Data (c) Anonymous Data (d) Other – please specify in the "Details" column If you answered "yes" to question 6(a) please contact ICODA@hdruk.ac.uk to discuss further. Personally Identifiable Data is not permitted in the ICODA Workbench 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 ICODA Workbench?		
1.8	If you answered "no" to question 1.7, will the Data Sets be stored in a Databank and accessible via the ICODA Workbench?		
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		

2. 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		

3. 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		

4. 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		