

**CONSENT DECLARATION APPLICATION FORM**

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**NOTE: Use only for seeking a consent declaration for processing[[1]](#footnote-1) personal data from the Central Statistics Office COVID-19 Data Research Hub[[2]](#footnote-2)**

**PLEASE NOTE**

* Detailed guidance on the application process to access the CSO COVID-19 Data Research Hub can be viewed on the [Health Research Board website](https://www.hrb.ie/data-collections-evidence/access-covid-19-data-for-research/) and by contacting the COVIDdatahub@hrb.ie.
* The HRCDC is a body formed under statutory instrument ([S.I. No. 314 of 2018](http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf) as amended by [S.I. No. 188 of 2019](http://www.irishstatutebook.ie/eli/2019/si/188/made/en/pdf) and [S.I No.18 of 2021](http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf)).
* The information provided by you in connection with this application form is subject to the [Freedom of Information Act, 2014](http://www.irishstatutebook.ie/eli/2014/act/30/enacted/en/pdf).
* All references to Regulations herein, are those cited in the [Health Research Regulations](http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf).
* All references to Articles herein, are those cited in General Data Protection Regulation (GDPR) [Regulation (EU) 2016/679.](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02016R0679-20160504)
* Specific links to GDPR Articles through <https://gdpr-info.eu/> is for information purposes and ease of reference only.
* Detailed data protection guidance can be viewed on the [Data Protection Commission](https://www.dataprotection.ie/en/dpc-guidance) website.
* Detailed guidance on the application process can be viewed on the [HRCDC website](https://hrcdc.ie/guidance/).
* Please do not provide surplus documentation unless specifically requested.
* Electronic signatures are acceptable.
* Please submit a non-scanned PDF (converted from Word).
* Please do not alter the content or lay out of the Application Form.
* **Please consult with data controller’s Data Protection Officer prior to submission.**

Version 4.2

Date January 2023

Owner: Secretariat, HRCDC

Reviewed by: HRCDC and CSO

Contact: Secretariat@hrcdc.ie

**PLEASE COMPLETE - MANDATORY**

In consultation with the Central Statistics Office (CSO), this application form has been adapted specifically for researchers accessing the COVID-19 Data Research Hub.

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| All completed sections in Yellow have been reviewed by the CSO for accuracy of information. These sections detail many of the CSO technical and organisational data protections safeguards that are specific to the COVID-19 Data Research Hub.These sections contain common information that will apply across all applications to the HRCDC, where researchers are seeking a consent declaration for accessing and processing COVID-19 Data. These sections DO NOT need to be completed.  |

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| All sections in Purple MUST be completed by the Applicant(s) |

Please confirm that ALL the following criteria are met before proceeding with this application form. Check all boxes that apply:

[ ]  The consent declaration being sought through this application process is specifically for the processing of personal data within Research Microdata Files (RMF) from the COVID-19 Data Research Hub only, and *no other personal data[[3]](#footnote-3)*.

[ ]  The Applicant has received confirmation from the Research Data Governance Board[[4]](#footnote-4) (RDGB) Secretariat, that a validated RDGB application has been scheduled for RDGB review.

 **OR**

[ ] The Applicant has received approval or conditional approval from the Research Data Governance Board regarding eligibility and recommendation to access COVID-19 Data Research Hub.

[ ] The researcher(s) directly involved with the research study accessing the COVID-19 Data Research Hub are, or will become, ‘Officers of Statistics’ under Section 20(c) of the Statistic Act,1993.

[ ]  The Data Controller research organisation is, or will be, registered with the CSO, subject to its approval.

[ ]  Research Ethics approval, or provisional approval pending a consent declaration, has been granted by a Research Ethics Committee(s).

[ ] A Data Protection Impact Assessment form has been completed for the research study and reviewed by the Data Protection Officer(s) with accompanying data protection advice.

**TITLE OF RESEARCH:**

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| **Provide a short title for the research Study**  |
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**LAY SUMMARY OF RESEARCH:**

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| 1. **Provide a non-confidential lay summary describing the research (Max 150 words)**

The lay summary will be used of the purpose of HRCDC public records. Please do not use overly technical language or commercially sensitive information. |
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**PART A: APPLICANT DETAILS**

*Regulation 5(4)(b)*

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| **Lead Data Controller name and contact details** ([Ref Art 4/GDPR](https://gdpr-info.eu/art-4-gdpr/))The Data Controller determines how and why personal data is being collected and used (processed) for the health research study. Please include the principal business of the Data Controller eg higher education institute, voluntary hospital, single GP, health service provider. |
| Name of organisation: Address: Website: Principal business: General role undertaken by Lead Controller in research study:  |

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| 1. **Applicant/Principal Investigator name and contact details**

If the Applicant is the Data Controller, solely in their personal capacity, this should be made clear, and information provided to support that view. eg sole trader, individual with private practice, not an employee of an organisation*.*  |
| Name:Address: Email: Telephone: [ ]  Data Controller |

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| 1. **Lead contact person to receive correspondence in relation to this application, if different from No. 2**
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| [ ]  As above: Name:Address: Email:Telephone:  |

*Regulation 5(4)(b)*

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| 1. **Joint Data-Controller(s) name and contact details** ([Ref Art 26/GDPR](https://gdpr-info.eu/art-26-gdpr/))

e.g. consider co-investigators, collaborators etc and others that may also be determining how and why personal data is being used (processed) for the study.  |
| [ ]  Not applicable Name of organisation:Name of lead Collaborator/Co-Investigator:Address/website:Principal business: Role undertaken by Joint-Data Controller in research study: *Repeat details above if more than one joint controller* |

*Regulation 5(4)(b)*

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| 1. **Joint Data-Controller(s): Please outline what arrangements are in place between the Joint Data-Controllers to reflect the roles and responsibilities** ([Ref Art 26/GDPR](https://gdpr-info.eu/art-26-gdpr/))

Example arrangements maybe data transfer agreements, inter-institutional agreements, contractual arrangements etc |
| [ ]  Not applicable Details:  |

*Regulation 3(1)(b)(iv)*

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| 1. **Data Processors(s) name and contact details** ([Ref Art 28/GDPR](https://gdpr-info.eu/art-28-gdpr/))

A Data Processor acts on the instruction of the Data Controller. e.g. consider sub-contractors, service providers, academic institutions carrying out testing/analysis on the instruction of the Data Controller. |
| [ ]  Not applicable Name of organisation:Name of lead contact:Address/website: Principle business:Role undertaken by Processor in research study: |

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| 1. **Controller-Processors: Please outline what legal agreements or legal acts are in place between the Controller(s) and Processor** ([Ref Art 28/GDPR](https://gdpr-info.eu/art-28-gdpr/))
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| [ ]  Not applicable [ ]  Other details:  |

*Regulation 3(1)(b)(v)*

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| 1. **Please specify any Sponsor/funder(s) for the research study**
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| [ ]  Not applicable Name of organisation:Name of Lead Contact:Address/website: Principle business:Role undertaken by Sponsor/funder in research study: |

*Regulation 3(1)(b)(vi)*

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| 1. **Please specify any third party (other than a joint data controller or data processor) with whom it is intended to share any of the data obtained (including where it has been pseudonymised or anonymised) and the purpose of such sharing.**
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| Research Microdata files (RMFs) will not leave the COVID-19 Data Research Hub. Researchers accessing the COVID-19 Data Research Hub must analyse the RMFs within the data portal. The datasets at all times remain on a CSO server. Only aggregated, analysed data approved by the CSO Data Custodian can be removed from the portal, at which point it will be irrevocably anonymised, as described in Part B, Section 7. |

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| 1. **Jurisdiction of data processing for the research**

(Ref: <https://www.dataprotection.ie/en/organisations/international-transfers>, [Ref Chapter V/GDPR](https://gdpr-info.eu/chapter-5/))  |
| Republic of Ireland only. Research Microdata files (RMFs) will not leave the COVID-19 Data Research Hub as outlined above. Only registered researchers from recognised research Institutions in Ireland are permitted to apply for access to these data. |

*Regulation 5(4)(c)(vii)*

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| 1. **Please list all Research Ethics Committees (RECs) involved in approval of the research and attach a copy of outcome letter from each REC**

NOTE: The HRCDC cannot consider applications if REC approval, or provisional approval, is not in place*.*  |
| Name of REC: Date of REC approval (or provisional approval): [ ]  Copy of REC approval(s) attached.[ ]  Confirmation that the REC approval specifically covers the health research study outlined in this application form[ ]  Copy of Applicant responses to queries raised by the REC(s)NOTE: Where the Applicant has received provisional approval from a REC and has responded to and addressed queries raised, please attach these responses when submitting the application. |
| 1. **Please confirm the status of the approval process with the Research Data Governance Board and attach a copy of outcome letter**

NOTE: The HRCDC cannot consider applications where none of the scenarios below apply.  |
| [ ]  RDGB application is validated and scheduled for RDBG review. [ ]  RDGB full approval granted, **OR**[ ]  RDGB conditional approval granted. [ ]  Copy of the RDGB decision letter attached. [ ]  Copy of Applicant responses to any queries raised or conditions applied by the RDGB.NOTE: Where the Applicant has received conditional approval from the RDGB and has responded to any queries, or addressed conditions, please attach these responses when submitting the application.  |

**PART B: NATURE OF HEALTH RESEARCH AND PERSONAL DATA BEING USED**

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| 1. **Indicate (i) the start date of the research and (ii) expected duration (months)**

This information assists with informing the HRCDC of the duration of the consent declaration, if made. |
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| 1. **Describe the nature, objective, and deliverables of the research (Max 1 Page)**

Please provide non-confidential information if possible. Please do not use overly technical language or commercially sensitive information. |
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| 1. **Provide an overview of the proposed design and methodology of the research (Max 2 Pages)**

Please complete Appendix I of this application form. Provide non-confidential information if possible. Do not use overly technical language or commercially sensitive information. Please include details of the number of anticipated participants in the research study. |
| [ ]  Appendix I completed  |

*Regulation 5(4)(c)(i)*

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| 1. **i)** **Describe the personal data which will be obtained and used for the research**

eg names, date of birth, age, gender, clinical data, phenotype data, addresses, economic data, ethnicity, NOTE: A detailed description of the Research Microdata File(s) being accessed, and the data contained within MUST be provided ([Ref Art 4/GDPR](https://gdpr-info.eu/art-4-gdpr/), [Ref Art 9/GDPR](https://gdpr-info.eu/art-9-gdpr/)) |
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| **ii)** **Identify the data sources from which the personal data will be obtained** eg Medical records, Hospitals, General Practice records Health Service providers, registries*,* databases, questionnaires, social media etc. |
| The Central Statistics Office (CSO) takes multiple data flows from the HSE during the Covid-19 pandemic. The incoming data are processed, pseudonymised and stored securely. The data is governed by the CSO Data Management Policy:(<https://www.cso.ie/en/media/csoie/foi/documents/CSO_Data_Management_Policy_Summary_2019.pdf>). Internally, in CSO, the data is stored in the source tier of the CSO Administrative Data Centre (ADC). From there, the data is made available to researchers by the Researcher Coordination Unit (RCU) via the Researcher Data Portal (RDP). Only designated Officers of Statistics can access the RMFs. The data flows are as follows:1. a2I\_src - HSE Coronavirus Assessments, Test Referrals and Facilities data2. C19HospitalCases\_src - COVID Cases in Hospitals for the Previous 24 Hours3. CIDR\_src - HSE Computerised Infectious Disease Reporting System4. HIPE\_src - Hospital Inpatient Discharge Data5. NOCA\_src - National Office of Clinical Audit Intensive Care Unit Data6. SBAR\_src - Situation, Background, Assessment, Recommendation. Shift handover data.7. CCT\_src - Covid Care Tracker data |
| **iii)** **Outline what engagement has occurred, general or specific, with the Data Controller of the data sources on the likelihood that they will provide the personal data should a consent declaration be made**  |
| The CSO is the Data Controller for the Health Service Executive data that is transferred in to the CSO. The Data controller of the study and researchers are engaged with the CSO and have, or will have, completed the following steps: **[TICK ALL THAT APPLY]**[ ]  The Data Controller organisation is registered with the CSO [ ]  Researchers are registered with the CSO[ ]  Researchers have completed CSO training[ ]  Researchers will become ‘Officers of Statistics’ pending approval by the CSO. [ ]  Research study has been deemed eligible and within scope for use the RMFs from the COVID-19 Data Research Hub, as determined by the CSO and the associated Research Data Governance Board (RDGB)[ ]  The researcher has submitted an application form to the CSO and RGDB and has received approval to continue their application for access to the COVID-19 Data Research Hub. [ ]  Other: **[PLEASE PROVIDE ANY OTHER INFORMATION]**Research Microdata Files (RMFs) are unit record files provided for statistical research purposes by the Central Statistics Office (CSO) under Section 20(c) of the Statistics Act, 1993. While RMFs do not contain direct identifiers, the risk of disclosure through indirect identification may be significant. The processes for authorising access to RMFs and for managing RMF research projects are therefore strictly controlled by the CSO.(<https://www.cso.ie/en/aboutus/lgdp/csodatapolicies/dataforresearchers/policies/#d.en.210341>)  |
| **iv)** **If relevant, outline what arrangements will be in place between the Lead Data Controller of the research study and the Data Controller of the personal data**eg data and material transfer agreement, memorandum of understanding, terms of use etc |
| All arrangements between the Data Controller of the research study and Data Controller (CSO) of the COVID-19 Data Research Hub are set out on the CSO ‘RMF Applications Procedure’ webpage:<https://www.cso.ie/en/aboutus/lgdp/csodatapolicies/dataforresearchers/rmfapplicationprocedure/> and the HRB ‘[Access COVID-19 Data Research Hub’](https://www.hrb.ie/data-collections-evidence/access-covid-19-data-for-research/)The researchers undertaking the study are/will be appointed as Officers of Statistics by the CSO under Section 20(c) of the Statistics Act, 1993 to perform the research as agreed under the terms of the RMF Standard Agreement. Researchers agree to abide by the protocols, terms and conditions of this Agreement. Failure to do so may result in sanctions being applied by CSO as follows:- Termination of the researcher’s appointment as an Officer of Statistics- Requirement to return and/or cease using all information provided by the CSO- Corresponding sanctions in relation to the organisation/institute and other RMF researchers in that organisation/institute- Denial of future requests for RMF research accessThe CSO reserves the right to apply other sanctions, up to and including prosecution under the Statistics Act, 1993, where appropriate.The Data Controller (Research Organisation) of the study that is seeking access to the RMFs must register with the CSO: * Only researchers employed by, or formally related to, a registered research organisation will be eligible to apply for access to RMFs using the RMF Application Form.
* The registered Data Controller (Research Organisation) must abide by the terms and conditions relating to the provision of access to RMFs.

Researchers: * must abide by the CSO RMF Policy
* https://www.cso.ie/en/aboutus/lgdp/csodatapolicies/dataforresearchers/policies/
* must follow by the CSO ‘Code of Practice’: <https://www.cso.ie/en/aboutus/lgdp/csodatapolicies/statisticalconfidentiality/codeofpractice/>
* must complete a Declaration of Secrecy as set out in Section 21 of the Statistics Act before access to an RMF is granted. The researcher is obliged by law to respect the statistical confidentiality of information contained in the RMF (Section 33) and may only use that information for statistical purposes (Section 32). Any breach of these requirements is an offence under Section 38 of the Act and may be subject to prosecution.
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| 1. **i)** **Describe the data processing activities that will be carried out during the life cycle of the research. A simple data flow diagram should be provided if possible** ([Ref Art 4(2)/GDPR)](https://gdpr-info.eu/art-4-gdpr/)

Consider activities such as: accessing, collecting, recording, storing, adapting, pseudonymisation, anonymisation, analysis, linking, combining, sharing, transfers, archiving and destruction  |
| * Access pseudonymised RMFs as permitted by the CSO
* Analysis of RMFs within the portal of the COVID-19 Data Research Hub, and in accordance with the Researcher User Guide and all relevant CSO policies and procedures.
* Analysed RMFs are exported as output files with the assistance of a CSO data custodian (statistician). The data custodian has access permission to the researcher's Research Data Portal output folder. The data custodian then checks the output file for compliance with statistical disclosure control before emailing the approved output to the researcher. The output file is recorded by CSO and linked to the research study.
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| **ii)** **To establish why a consent declaration being sought, please outline what specific data processing activities will be carried out, without the explicit consent of the research participants** |
| [ ]  As above Specifically: |

*Regulation 5(4)(c)(i)*

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| 1. **Explain why the research requires that personal data be obtained and processed rather than fully/irrevocably anonymised data**

**NOTE:** pseudonymised or de-identified data may also be considered personal data ([Ref Recital 26/GDPR](https://gdpr-info.eu/recitals/no-26/))  |
| No directly identifiable data relating to individuals will be made available by the CSO to the researchers. If anonymised data could sufficiently address research needs, there would not be a requirement for RMF access to COVID-19 data. The process of anonymising data destroys most, if not all, of the value of the data in terms of potential research insight. Therefore, pseudonymised RMFs where no directly identifiable data is available, is used to minimise the risk while also preserving the research data. Pseudonymised data carries a small residual risk of indirect identification. RMFs are not statistical products. Unlike statistical products which relate to aggregated statistical analysis, RMFs are not published or made available to the general public. In RMFs, there remains a residual risk of indirect disclosure. For this reason, safeguards and precautions are put in place.  |

*Regulation 5(4)(c)(ii)*

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| 1. **Describe how you will ensure that personal data will not be processed in such a way that damage or distress is, or is likely to be, caused to the participant**
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| * Significant safeguards are implemented by the CSO as per its Data Management Policy, Codes of Practice, and requirement of all researchers to be formally approved as an ‘Officer of Statistics’.
* All RMFs are pseudonymised
* The pseudonymisation process involves removing personal data such as patient's name, address, date of birth and contact details. Identifiers are replaced with a Protected Identifier Key (PIK) to allow safe linkage across data sources and over time. To compensate for the lack of a standard common identifier on all health records and all data sources, a new PIK variable has been created combining the patient's date of birth and surname to enhance data linkage using Protected Identifier Keys. Protected Identifier Keys use either a randomised lookup table or a salt and hash technique where access to key parts of the pseudonymisation process is closely guarded.
* A single copy of pseudonymised RMFs is transferred to a drive controlled by Research Coordination Unit staff, who make the data available to approved researchers. External researchers access the pseudonymised data through the CSO Research Data Portal.
* It is not possible for researchers to export RMFs from the Research Data Portal. All outputs are checked by a CSO statistician to ensure data confidentiality and compliance with the CSO Statistical Disclosure Control policy. Therefore, the risk of indirect identification is removed at the output-checking stage of the process.
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*Regulation 3(1)(c)(iii)*

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| 1. **Describe how you will ensure that only the minimal amount of personal data will be collected and used, and the personal data will go no further than is necessary for the purpose of attaining the research objective**

This question relates specifically to the data minimisation principle ([Ref Art 5(1)(c)/GDPR](https://gdpr-info.eu/art-5-gdpr/)) |
| * The CSO applies a principle of data minimisation when assessing applications for access to RMFs.
* The information provided to the researcher will be limited to those topics/variables which are necessary for the specific research study.
* The pseudonymisation process outlined in Section 7 is applied to remove personal data such as patient's name, address, date of birth and contact details.
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*Regulation 5(4)(c)(iv)*

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| 1. **Confirm that there will be no disclosure of the personal data, unless that disclosure is required by law, or the participant has given his or her explicit consent to the disclosure**
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*Regulation 5(4)(d)*

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| 1. **If the research involves linking the personal data with different sources of information, please describe what is involved and its purpose**

eg Please specifically comment as to whether the data linkage activity is being carried out within the CSO Data Portal and what this entails.  |
| Persons appointed as Officers of Statistics are not permitted to match/link (at a micro level) the RMF to any other non-CSO data source. Linkage to other CSO data sources is only permissible subject to the written agreement of the CSO. Any dataset derived from a CSO RMF by means of such linkage is subject to the same confidentiality requirements and conditions of use which apply to the original RMF.[ ]  No linkage [ ]  Linkage within CSO COVID-19 Data Research HubDetails:  |

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| 1. **i)** **Describe your exit strategy whereby the research study will no longer require a consent declaration**

Consider at what stage during the research study personal data will be rendered irrevocably anonymised to the Data Controller(s), returned or destroyed, or when future consent may be obtained etc. Where relevant, consider at what point the master list/key that codifies the personal data, will be destroyed. If a consent declaration is required over several years, or indefinitely, please set out the reasons why.  |
| A consent declaration will no longer be required when:* the analysis of the RMFs is completed and
* the researcher is no longer an Officer of Statistics under the CSO and access to the COVID-19 Data Research Hub is terminated.

Once the analysis of the RMFs is completed, the ‘output’ of the analysis can be exported as an ‘output file’. The CSO data custodian (statistician) has access permission to the researcher's RDP output folder. The data custodian then checks the output file for compliance with statistical disclosure control before emailing the approved ‘output file’ to the researcher. The output file is recorded by CSO and linked to the research study.NOTE: It is only permissible to take non-confidential or fully anonymised aggregate data out of the Research Data Portal. The relevant CSO Statistician/Senior Statistician will review data ‘output’ aggregates from the Research Data Portal to check that they are non-confidential in nature. The relevant CSO Statistician/Senior Statistician will review aggregates from the RDP to check that they are non-confidential in nature. These must be assessed in the context of all available aggregate information to guard against disclosure through comparing different aggregates. |
| **ii)** **Provide a specific timeline as to when access to the CSO COVID-19 Data Research Hub is no longer required and therefore a consent declaration, if made, will no longer be required**To determine the duration of a consent declaration, if made, please provide as much detail as possible. CHECK the box below, if this statement applies. |
| Details: [ ] \*An Officer of Statistics term is for a one 1 year. If access to the COVID-19 Data Research Hub is required beyond this timeline and a consent declaration is required for longer than a year, Officer of Statistics appointment will be renewed in accordance with CSO procedures.  |

**PART C: CONSENT**

*Regulation 5(4)(e)*

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| 1. **Why is it not possible to seek consent from the research participant(s) to process their personal data for this research study?**

Please substantiate the rationale with supporting evidence where possible. Consider the HRCDC guidance notes.  |
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| 1. **In what way was consent from the participant(s) formally considered at the design stage or any stage of the research?**

eg was consent discussed with a research ethics committee, subject matter experts, collaborators, participant advocacy or representative groups etc.  |
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| 1. **What Public, Patient and Carer involvement activity (PPI) has been or, will be undertaken with focus groups, advocacy groups, patient and/or representative participants regarding:**

NOTE: PPI activity is considered an important data protection safeguarding activity, to gain representative perspectives and opinions where participants themselves cannot provide explicit consent. PPI activity also provides a valuable and meaningful way of seeking views on the support for and development of the research. This PPI engagement can further inform what transparency measures can be implemented and how, which itself is an important data protection principle. |
| 1. **the feasibility of obtaining consent:**

[ ]  None, explain why:  |
| 1. **support for, and development of the research:**

[ ]  None, explain why:  |
| 1. **other comments:**
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| 1. **Will consent from the participant(s) be sought at any stage during the research study?**

eg If deferred consent can be obtained, please expand further.  |
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**PART D: THE PUBLIC INTEREST CASE**

*Regulation 5(4)(e)*

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| **Describe fully why you believe that the public interest in carrying out the health research significantly outweighs the public interest in requiring the explicit consent of the participant and provide any supporting evidence for your case (Max 500 words)**It is essential to provide a detailed, thorough response to this question as the public interest case for the research is a key element that facilitates the HRCDC in making its decision. The response should outline how the research may best impact and serve the interests of the participants and public, specifically and/or more generally. Please provide supporting documentation where appropriate. |
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**PART E: LEGAL BASIS FOR THE PROCESSING OF PERSONAL DATA**

*Regulation 5(4)(a)(i), Regulation 5(4)(a)(ii)*

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| **Identify the legal basis under Article 6 and the relevant condition under Article 9 for the proposed processing of the personal data** (Ref [Art 6/GDPR](https://gdpr-info.eu/art-6-gdpr/) & [Art 9/GDPR](https://gdpr-info.eu/art-9-gdpr/) & [DPC Guidance](https://www.dataprotection.ie/sites/default/files/uploads/2020-04/Guidance%20on%20Legal%20Bases.pdf))Please consult with the Data Controller’s Data Protection Officer as necessary. |
| 1. **Article 6 legal basis:**
2. **Article 9 condition:**
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**PART F: INFORMATION REQUIREMENTS, DATA SECURITY ARRANGEMENTS AND TRAINING**

*Regulation 3(1)(d)*

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| 1. **Specify the transparency arrangements that are/will be in place to ensure that personal data are processed for the health research study in a transparent manner** ([Ref Art 5(1)(a)/GDPR](https://gdpr-info.eu/art-5-gdpr/))

Transparency is an important data protection principle, especially in circumstances where consent cannot be obtained. Consider what transparency measures will be implemented to inform participants/public about this specific study and the processing of data within this study. eg data protection policies, public notices, publicity campaigns, information leaflets, websites, engagement with representative patient/advocacy groups etc*.* Please provide supporting documentation where possible. |
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*Regulation 3(1)(c)(iv)-(viii)*

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| 1. **Identify the technical and organisational measures/arrangements in place to:**
2. **limit access to the personal data being processed, to prevent unauthorised consultation, alteration, disclosure or erasure of personal data**
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| The CSO technology in facilitating secure access to RMFS is in keeping with best practice internationally. The CSO has a secure remote access system in place for access to RMFs as well as an application process which involves the researcher and research organisation registration before an application for access to RMF data will be considered. The secure remote access system, the Researcher Data Portal (RDP) is a locked-down Citrix system from which no data can be extracted without the approval of CSO. The RDP was developed under the headings of the Five Safes:* Safe Projects (RMF approval process),
* Safe People (Researcher and Research Organisation registration process),
* Safe Settings (RDP security),
* Safe Data (RMF construction in compliance with CSO Statistical Disclosure Control policy) and
* Safe Outputs (Outputs checked in accordance with CSO Statistical Disclosure Control policy by Data Custodian)

The RDP was launched by CSO in 2017. In 2019, 489 researchers were approved for RMF access using the RDP. There were no security or performance issues. |
| 1. **log persons who access and process the personal data**
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| The CSO has a stringent registration and approval process for third parties accessing the RMFs. Only researchers who are employed by, or formally related to, a registered research organisation will be eligible to apply for access to RMFs. All researchers are appointed Officers of Statistics for a specific period.  |
| 1. **to prevent unauthorised access to the device used to access the Research Data Portal by any person who is not an Officer of Statistics**

Detail the security measures in place to protect the PC/device used to access the portal, describe the location of the device used, security of device, access to the device, building security etc*.*  |
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| 1. **protect the security of the personal data concerned**

eg encryption techniques, passwords, pseudonymisation techniques, firewalls etc.  |
| Researchers access the CSO Researcher Data Portal (RDP) via a Citrix connection using a unique username and a password which must be reset at time of first login. A PIN generated from soft token authentication is required to log in to the Research Data Portal.The service must only be accessed from a secure location. CSO requests the IP address of the researcher/institute prior to account set-up and access may be restricted based on the specified domain which must be a main fixed business IP address. With the agreement of CSO, the researcher may connect remotely to this IP address via virtual private network (VPN). The RDP is a locked-down Citrix environment from which it is not possible for the researcher to export or import data. The microdata, at all times, remains on a CSO server. There is no email facility or internet access from the RDP.Hardware used: * CSO servers for data storage (maintained by CSO IT)

Software:* Citrix (for running the RDP)
* R/R Studio, STATA, SPSS, and ArcGIS (for researcher use)
* Microdata Portal (internal CSO database for storage of administrative data relating to researchers’ RMF project applications)

Pseudonymisation techniques are applied to all COVID-19 data, as described in PART B, Section 7 of this application form.  |
| 1. **anonymise, archive or destroy personal data once the research study has been completed**

Please consider how the data will be further safeguarded by for example, destroying the master list/key, deleting or returning personal data etc*.* |
| The RMFs are under the control of the CSO and therefore anonymisation, archiving or destruction of personal data associated with the RMFs will be carried out in accordance with its procedures.  |
| 1. **Outline any other technical and organisational measures in place, together with processes for testing and evaluating the effectiveness of such measures, to ensure data processing is in accordance with the data protection legislation** ([Ref Recital 78/GDPR](https://gdpr-info.eu/recitals/no-78/), [Art 32/GDPR](https://gdpr-info.eu/art-32-gdpr/))
 |
| It is only permissible to take non-confidential or fully anonymised aggregate data out of the Research Data Portal. The relevant Statistician/Senior Statistician will review aggregates from the Research Data Portal to check that they are non-confidential in nature. These are assessed in the context of all available aggregate information to guard against disclosure through comparing different aggregates. |

*Regulation 3(1)(b)(vii)*

|  |
| --- |
| 1. **Provide information on the training in data protection law and practice that has been provided to those individuals involved in carrying out the research**.
 |
| The researchers will undergo specific training with the CSO regarding access and ensuring security of the RMFs, once approved as an Officer of Statistics.Data protection training, or other:  |

*Regulation 3(1)(c)(i)&(ii), Regulation 5(4)(c)(vi), Regulation 5(4)(d),*

|  |
| --- |
| 1. **i)** **Summarise the findings of the Data Protection Impact Assessment (Max 500 words)**

Please attached a copy of the DPIA. Where there are joint data controllers, a single DPIA will suffice, but the advice of each joint data controller’s DPO must be attached.  |
| [ ]  Copy of DPIA attachedSummary of Assessment:   |
| **ii)** **Outline or attach the advice of the Data Protection Officer(s) (DPO) regarding the data protection risks of the research study**Please outline any specific risks highlighted by the DPO, and advice provided to mitigate any risks*.* |
| Name of DPO #1:[ ]  Advice of DPO#1: Name of DPO #2:[ ]  Advice of DPO#2: |
| **iii) Indicate the steps taken to address any risks identified, and/or action taken in relation to advice provided by the DPO** Please specifically reference any data protection risks identified if data linkage is being carried out and where possible provide details of any consultations undertaken with research participants whose data is being linked.  |
|   |

**SIGNATURE PAGE TO FOLLOW**

**PART G: SIGNATURES - DATA CONTROLLER(S)**

DATA CONTROLLER #1

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| --- |
| I, the Applicant, hereby declare that: [ ]  I am duly authorised by my organisation (Data Controller), [ ]  I am the duly authorised Data Controller,to submit this application to the Health Research Consent Declaration Committee. To the best of my knowledge all the information provided herein**[[5]](#footnote-5)** is correct. I hereby understand that any decision made by the HRCDC is based on the accuracy of the information provided herein, or any subsequent information provided to the Health Research Consent Declaration Committee.  |
| Applicant Name:Organisation: Title: Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:Read and acknowledged by an authorised representative within the Organisation of the Applicant: *[this must be an appropriate and competent authority eg Data Protection Officer, Legal Counsel]*Name: Title: signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: |

DATA CONTROLLER #2

|  |
| --- |
| I, the Applicant, hereby declare that: [ ]  I am duly authorised by my organisation (Data Controller), [ ]  I am the duly authorised Data Controller,to submit this application to the Health Research Consent Declaration Committee. To the best of my knowledge all the information provided herein[[6]](#footnote-6) is correct. I hereby understand that any decision made by the HRCDC is based on the accuracy of the information provided herein, or any subsequent information provided to the Health Research Consent Declaration Committee.  |
| Applicant Name:Organisation: Title: signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:Read and acknowledged by an authorised representative within the Organisation of the Applicant: *[this must be an appropriate and competent authority eg Data Protection Officer, Legal Counsel]*Name: Title: signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: |

**APPENDIX - I**

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| **PART B, Section 3: Design & Methodology of Research (Max 2 Pages)** |
|   |

1. Data Processing: carrying out the following with personal data: eg accessing, collecting, recording, storing, adapting, pseudonymisation, anonymisation, analysis, linking, combining, sharing, transfers, archiving and destruction. ([Ref Art 4(2)/GDPR)](https://gdpr-info.eu/art-4-gdpr/) [↑](#footnote-ref-1)
2. This application form has been adapted in consultation with the Central Statistics Office <https://www.cso.ie/en/>. All completed sections in Yellow have been reviewed by the CSO for accuracy and are common across all applications to the HRCDC, seeking a consent declaration for accessing and processing CSO COVID-19 Data. Further information can be found at: <https://www.hrb.ie/data-collections-evidence/access-covid-19-data-for-research/> [↑](#footnote-ref-2)
3. Where personal data from other sources (non-COVID-19 Data Research Hub) is also being processed, please do not complete this application form as it will not be considered by the HRCDC. Instead, you must complete the standard HRCDC application form available at: <https://hrcdc.ie/apply/#b-2> [↑](#footnote-ref-3)
4. The RDGB is an independent body established jointly by the Health Research Board (HRB) and the CSO in close collaboration with the Department of Health (DOH). Further information can be found at: <https://www.hrb.ie/data-collections-evidence/access-covid-19-data-for-research/> [↑](#footnote-ref-4)
5. The declaration made by the Applicant is specific to the information provided by them, and not to the information already provided in sections marked yellow. [↑](#footnote-ref-5)
6. As above [↑](#footnote-ref-6)