Research Data Governance Board (RDGB)

Guidance Notes

to support an application for access to the COVID-19 Data Research Hub (Research Microdata Files)

**Call open to Applicants from 3 March 2021**

This is a rolling call for submission to the Research Data Governance Board (RDGB)

This Application Form must be completed by the Lead Researcher and submitted by email in .doc format to COVIDDatahub@hrb.ie. Section C, the declaration, must be countersigned by the Research Organisation’s RMF Contact.

**Note:** It is strongly recommended that applicants contact the CSO Researcher Liaison in advance of submitting their application to the RDGB Secretariat. This step will be particularly beneficial at the project formation stage to discuss aspects related to project feasibility and clarify further queries concerning both project and data specifications and will enable applicants to submit a refined application for RDGB review.

The CSO has nominated a dedicated Researcher Liaison who can provide provisional advice to researchers on the available COVID-19 datasets and on the CSO safeguards and protocols in advance of submitting an RDGB application.

Please contact:Sanela Smith, CSO Statistician email: c19researchinfo@cso.ie

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**Last updated:** May 2021

**Owner:** Secretariat: Research Data Governance Board

**Contact:** COVIDdatahub@hrb.ie

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1. Background

In accordance with the Statistics Act, 1993, the Central Statistics Office (CSO) hosts a secure COVID-19 Data Research Hub which contains individual level administrative datasets obtained from the Health Service Executive (HSE). The datasets within the Research Hub contain pseudonymised individual level data on those who have been diagnosed with COVID-19, been referred for testing, been treated in hospital for COVID-19 or have been identified as being a close contact of a confirmed case.

Previously, only certain CSO staff had access to these Research Microdata Files (RMF) for statistical purposes and it was shared with named individuals involved in the Irish Epidemiological Modelling Advisory Group (IEMAG) of the National Public Health Emergency Team (NPHET).

After extensive consultation, the Health Research Board (HRB) is collaborating with the Department of Health (DoH), and the CSO to make this data available in a format that is controlled, accessible and usable for approved researchers to inform evidence-based decision making during this period of national emergency.

Robust processes and safeguards have been put in place by all partners, in addition to the existing research-related approvals, in order to preserve patient privacy and confidentiality which is at the forefront of thinking on this initiative.

Optimising the secure access to and use of COVID-19 data brings Ireland in line with most countries, and with the prevailing policy direction in Europe.

1. Structure and Contents of the CSO COVID-19 Data Research Hub

The COVID-19 Data Research Hub is maintained by the CSO and daily updates are incorporated from the main HSE Covid-19 administrative data sources. Currently, the following main RMFs/data flows are available in COVID-19 Data Research Hub for research purposes

1. HSE coronavirus assessments, test referrals and facilities data (a2I\_src)
2. COVID Cases in Hospitals for the Previous 24 Hours (C19HospitalCases\_src)
3. C19 COVID Care Tracker Application Data Source Tier (CCT\_src)
4. HSE Computerised Infectious Disease Reporting System (CIDR\_src)
5. Hospital Inpatient Discharge Data (HIPE\_src)
6. National Office of Clinical Audit Intensive Care Unit Data (NOCA\_src)
7. Situation, Background, Assessment, Recommendation, Shift Handover Data (SBAR\_src)
8. COVID-19 Vaccine Data

Each of these main RMFs/data flows contain several different datasets and each of the datasets contain set of different data variables. Please see the structure below

Once in receipt of HSE data, the CSO converts the identifier numbers in each dataset to a Protected Identifier Key (**PIK**). The PIK is a unique and non-identifiable number which is internal to the CSO. Using the PIK enables the CSO to link and analyse data for statistical purposes, while protecting the security and confidentiality of the individual data.

1. Eligibility criteria

Access to the CSO COVID-19 Data Research Hub is restricted to registered researchers from registered research organisations in Ireland.

Applications for access will not be considered from commercial bodies.

The existing processes in place for allowing access to COVID-19 Data Research Hub are pertinent for applicants based in the Republic of Ireland (ROI) only. Only Researchers and Research Organisations registered with the CSO and based within ROI can apply for access to data that exists in the COVID-19 Data Research Hub. CSO have established data protocols, safeguard mechanisms, limitations and policies in place around providing data access. Primarily all the data in the COVID-19 Data Research Hub will reside in ROI and data will be accessed through the CSO virtual environment and will be further subject to internal audit.

In order to expedite the RDGB application process the CSO will undertake the registration of research organisations and researchers in parallel to the RDGB application process. Applications received by the RDGB will only be scheduled for discussion at RDGB meetings following confirmation from the CSO that the registration process is confirmed or underway.

1. The Research Data Governance Board

In addition to the usual protocols and technical safeguards adopted by the CSO, a new feature is the establishment of a Research Data Governance Board (**RDGB**) by the HRB and the CSO in close collaboration with the Department of Health (**DOH**) in Ireland.

The RDGB is an independent body set up as an additional safeguard in the application process to act as a central point for application receipt, screening, review and prioritisation of data requests prior to applications being assessed by the CSO. The RDGB will oversee a transparent process to facilitate secure and controlled access to the data for the purposes of conducting statistical analysis to facilitate research. The membership draws a wide range of expertise in secondary data analysis, COVID-19 research, CSO protocols and safeguards and existing governance, safeguards and best practices for research. The RDGB Secretariat is provided by the HRB and supports the RDGB in all aspects of its work. Read more information on the Research Data Governance Board.

Only applications that have been approved by the RDGB and where evidence of both Research Ethics Committee (**REC**) approval and a consent declaration from the Health Research Consent Declaration Committee (**HRCDC**; [www.hrcdc.ie](http://www.hrcdc.ie)) is received by the RDGB will be recommended to be reviewed by the CSO. The CSO will issue final approval for access to relevant COVID-19 health data.

1. Application and Review Process

The CSO actions to provide access to data to approved researchers for statistical analyses to facilitate research project is conducted under the Statistics Act. The RDGB is an added safeguard to support governance and transparency of this process under the Data Protection Act. Furthermore, health research involving human subjects must also be governed according to prevailing international best practice and ethical principles. In addition, data aspects of health research projects are regulated according to the Health Research Regulations of the 2018 Data Protection Act and researchers are required to have Research Ethics Committee (**REC**) approval for health research projects and a declaration from the Health Research Consent Declaration Committee (**HRCDC**) in events where personal data is accessed but where explicit consent of the data subject is not possible or practicable. Therefore, ALL the necessary protocols and safeguards to ensure compliance and best practice under both the Statistics Act, the Data Protection Act/ Health Research Regulations are all purposefully integrated into this single, collaborative process.

The HRB and the CSO have developed a dedicated and streamlined application form and process for researchers to make the case to the RDGB for access to the COVID-19 Data Research Hub. Researchers will find the application form, along with detailed Guidance on completing the form and process, on the HRB website.

The RDGB will oversee a transparent process to facilitate secure and controlled access to the data for the purposes of conducting statistical analyses to facilitate research by:

* Determining the eligibility of the Applicants, both individual applicants and the research organisations.
* Determining the validity of the research in addressing COVID-19 related research.
* Proving recommendations to the CSO on access its supported service to use the COVID-19 Data Research Hub.
* Ensuring that other regulatory approvals for the research projects are secured (Research Ethics approval; Consent Declarations from the Health Research Consent Declaration Committee).
* Monitoring the demand for and the use of the Irish COVID-19 Data Research Hub and it’s supporting CSO service.
* Informing wider discussion on the importance of optimising the use of health and social care data and/or statistical data for research purposes and progressing a health data access and linkage service for Ireland.

The RDGB is committed to an open process to ensure the integrity of the assessment process, conflict of interest and confidentiality are applied rigorously in each stage of the process.

The RDGB secretariat, on receipt of a valid application form, will forward the application to the CSO if it is within scope. The CSO will carry out a further preliminary review of the application and notify the RDGB secretariat whether it is feasible and within CSO scope for consideration.

The RDGB secretariat will then inform the researcher if the access request is being progressed for review by the RDGB and the researcher will be advised to seek (if they have not already done so) both Research Ethics Committee (REC) approval for the proposed project and to secure a declaration from the Health Research Consent Declaration Committee.

The RDGB will convene to consider applications, according to agreed criteria (Please see below in Section 5.1) and will confirm for the CSO that an application is for a health research project and is in-scope as a COVID-19-related research project.

Following a positive recommendation by the RDGB, and if the researcher provides documentation to the RDGB demonstrating receipt of approval from a REC and HRCDC, the application will be forwarded by the RDGB secretariat to the Researcher Co-ordination Unit of CSO for final approval using the robust protocols and safeguards inherent in the CSO RMF process.

* The researcher will be required to sign a Declaration of Secrecy and will then be appointed an Officers of Statistics for the purpose of their research project.
* The researcher agrees to abide by the terms and conditions of the CSO RMF Standard Agreement and completes CSO researcher training which reinforces the terms and conditions of the RMF Standard Agreement.

It should be noted that it is the Director General of the CSO who makes the final determination as to whether or not the research is in the public interest and within the scope of the Statistics Act,1993.

**5.1 RDGB Review Criteria**

To allow consistent RDGB decision making, the following review criteria will be used to guide and review each application under consideration, aligned with this Guidance for applicants, and information solicited in the application form:

* **Team and infrastructure:** relevant and appropriate experience of Lead Researcher, wider team, and organisational supports **i**ncluding security measure**s.**
* **Project focus:** relevant to COVID-19. Reason for access to RMF(s) is clear and follows the principle of data minimisation for this study**.**
* **Outputs and disseminations:** Potential benefits to public/patients or wider community, appropriate outputs proposed, and dissemination appears appropriate.
* **Feasibility:** no major concerns identified.
* **Declaration of interests/conflicts of interests:** disclosed/managed.
* **Other:** any other concerns that would negatively impact the project.
1. CSO Technical Safeguards

Where the Director General of the CSO approves a research project, the researcher then gains access to the specific datasets required for their research via the CSO Researcher Data Portal (RDP).

The CSO technology in facilitating secure access to microdata is in keeping with best practice internationally. The RDP is a locked-down Citrix environment from which no data can be extracted without the approval of the CSO. The researcher logs on using a unique username, PIN and password – as well as this, the researcher’s access may be restricted to a specific IP address. The microdata, at all times, remains on a CSO server. 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 CSO is the data controller for the datasets within the COVID-19 Data Research Hub and has finalised a Data Protection Impact Assessment (DPIA) with no concerns arising.

Successful applicants are appointed Officers of Statistics and are subject to a range of stringent conditions under the Statistics Act 1993. Thus, every appointment of an Officer of Statistics under Section 20(c) is:

* Personal to the named researcher;
* For the specified statistical project only;
* For access to specified RMF(s) only; and
* Time-bounded: All appointments specify an end-date on which access to the specified RMF(s) will cease.

The researcher must complete a Declaration of Secrecy as set out in Section 21 of the Statistics Act before access to the 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.

Access to the RMF, where granted, will only be provided once the researcher(s) has:

* been appointed as an Officer of Statistics,
* signed the Declaration of Secrecy,
* formally agreed to abide by the CSO RMF Standard Agreement, and
* attended a researcher training course provided by CSO.

This training course provides a comprehensive reinforcement of the RMF agreement conditions which the researcher has accepted. This course also sets out the legal obligations under the Statistics Act, 1993 which a researcher undertakes when appointed as an Officer of Statistics.

1. General Data Protection Regulation

The General Data Protection Regulation (GDPR) came into force on 25 May 2018.

The RDGB uses the information you provide (regarding all applicant team members) to consider your application, contact you about your application, and if you are successful, to manage your access throughout its lifetime including include contacting you with regard to monitoring of progress. Your application form will be shared with person(s) based in the Central Statistics Office (CSO).

We will publish some basic information on successful applications including Lead Researcher, Research Organisation, and lay summary on our website and may highlight individual applications or researchers in more detail (with specific consent). We will also use the information you have provided to generate general statistics around the overall use of the COVID-19 Data Research Hub, and to evaluate our mechanisms. After your access has ended, we will continue to keep your information on file to allow us to evaluate the outcomes, outputs and impacts of RDGB work.

Please note that we will also use information associated with unsuccessful applications for a number of the purposes outlined above such as generating general statistics around demand for secondary re-use of COVID-19 data, and to evaluate our mechanisms e.g. demographics of applicants, research areas of applicants.

1. Conflict of Interest

Conflict of interest (COI) rules *are applied rigorously in the RDGB process.* To ensure the integrity of the assessment process, conflict of interest rules and confidentiality are applied rigorously within the RDBG process. RDGB members will be requested to check their assigned application reviews and advise the RDGB secretariat and Chair if they identify any instances of COI in advance of the scheduled meeting.

Reviewers with the same institutional affiliation will recuse themselves from the discussion of that application.

A conflict of interest applies

* If a reviewer was involved in the preparation of the application.
	+ Stands to benefit directly should the application be accepted or rejected.
	+ Is in some way related to the applicant, co-applicant, collaborator, or sponsors (where applicable) at a personal or professional level.
	+ Is a former supervisor of the applicant, co-applicant, or sponsor (up to 5 years previously).
	+ Is a former collaborator of the applicant (up to 5 years previously).
	+ Is or has been in the past associated with a commercial enterprise which could be perceived as having a conflict of interest.
1. Timeframe

**Application Call:** This call will be open to applicants from March 2021. It is a rolling call with validated, in-scope applications (as initially reviewed by the RDGB Secretariat and the CSO) being scheduled for monthly RDGB meetings. The Lead Researcher will be informed once his/ her application is tabled for an RDGB meeting.

**RDGB Secretariat Preliminary Review:** Approximately 2-3 Days

**CSO Preliminary Review:** Approximately 2-3 Days

**RDGB Review Process**: Approximately 4-6 weeks (depending on scheduling of meetings)

**CSO Review Process:** Approximately 3-5 weeks

**RDGB Meeting Dates:** Please find meeting schedule published on RDGB webpages.

[**https://www.hrb.ie/data-collections-evidence/access-covid-19-data-for-research/research-data-governance-board-rdgb-meetings-and-decisions/rdgb-meetings/**](https://www.hrb.ie/data-collections-evidence/access-covid-19-data-for-research/research-data-governance-board-rdgb-meetings-and-decisions/rdgb-meetings/)

1. RDGB Secretariat Contact

**Email:** COVIDdatahub@hrb.ie

**Website:** <https://www.hrb.ie/data-collections-evidence/access-covid-19-data-for-research/about/rdgb-secretariat/>

**HRB Programme Manager:** Dr Caitriona Creely

**HRB Programme Officer:** Dr Sharon Kappala

**11 CSO Researcher Liaison Contact**

**Email:** c19researchinfo@cso.ie

**CSO Statistician:** Sanela Smith

***The RDGB reserves the right to reject any application that does not meet the terms of this call.***

1. Detailed Guidance on the Application Form

The Health Research Board (**HRB**) and the Central Statistics Board (**CSO**) have developed a dedicated and streamlined application form and process for researchers to apply for access to Research Microdata Files (**RMF**) within the COVID-19 Data Research Hub.

* These Guidance Notes have been prepared to assist the health research community with making an application to the Research Data Governance Board (RDGB) for access to the CSO COVID-19 Data Hub.
* The notes provide guidance on the various sections of the application form and how it should be approached.
* It is advised to be open and informative when providing answers so that the RDGB has the necessary information to fully consider the application. This will avoid the Secretariat and/or RDGB requesting further information and resulting in a delayed decision.
* Please ensure all questions are fully considered and adequately addressed to ensure completeness and quality and facilitate the RDGB to forming a decision.
* This Application Form must be completed by the Lead Researcher and submitted by email in .doc format to the RDGB Secretariat at COVIDDatahub@hrb.ie.
* Section C, the declaration, must be countersigned by the Research Organisation’s RMF Contact (or proposed RMF contact).

Initial Mandatory Checklist

Initially, the Lead Researcher will be asked to complete a check list of mandatory questions. The Lead Researcher must satisfy the conditions of this check list.

|  |
| --- |
|[ ]  Your Research Organisation must already be registered or agree to register with the Central Statistics Office for the purpose of accessing Research Microdata Files (RMFs) before submitting this application. See [https://www.cso.ie/en/aboutus/lgdp/csodatapolicies/dataforresearchers/forms/](https://www.cso.ie/en/aboutus/lgdp/csodatapolicies/dataforresearchers/forms/%20) for further information and application form. |
|[ ]  All researchers named on the Application Form must already be registered or agree to register with the Central Statistics Office. For each named researcher, if he or she has not previously been appointed as a Central Statistics Office (**CSO**) Officer of Statistics he or she must complete a separate Researcher Registration Application Form: <https://www.cso.ie/en/aboutus/lgdp/csodatapolicies/dataforresearchers/forms/> |
|[ ]  Ethical approval must be sought and obtained before final access is granted to the COVID-19 Research Microdata File (**RMF**). The Lead Researcher must provide evidence of such approval to the Research Data Governance Board before it makes a recommendation to the Central Statistics Office.  |
|[ ]  A consent declaration from the Health Research Consent Declaration Committee (**HRCDC**) must be sought and obtained before final access is granted to the COVID-19 Research Microdata File (**RMF**). The Lead Researcher must provide evidence of such approval to the Research Data Governance Board before it makes a recommendation to the Central Statistics Office.  |
|[ ]  I am aware that all applicants who are granted access to the COVID-19 Data Research Hub will be required to publish a Data Note on the HRB Open Research Platform following the successful completion of the research project as per HRB guidelines.  |
|[ ]  Do you give permission for RDGB Secretariat to share your application information with HRCDC following successful outcome at the RDGB review meeting? See HRCDC guidance on applying for a consent declaration and application form at <https://hrcdc.ie/apply/> A dedicated HRCDC application form has been developed to facilitate applying for a consent declaration for the purpose of processing RMFs from the COVID-19 Data Research Hub. |

Further details for completing each of the main sections of the application form are provided below:

APPLICATION FORM GUIDANCE

Title of the Research Project

You are asked to provide a title that clearly describes the project to which this application is related. This should be descriptive and concise and should reflect the aim of the project.

Lay Summary of the Research Project

The lay summary should be written as a plain English summary, such that it is clear, easy to understand, and is easily accessible to a broad, lay audience. Avoid the use of highly technical terms or commercially sensitive information. This summary may be used when providing information to the public concerning the research questions that are being asked and answered by the secondary re-use of COVID-19 Data. The word count is **150 words.**

Additional Approval Requirements

To access the Research Microdata Files (RMF) within the CSO COVID-19 Data Research Hub the Lead Researcher must obtain RDGB approval, and he/ she must also seek and obtain ethical approval from a Research Ethics Committee (REC) and a consent declaration from the Health Research Consent Declaration Committee (HRCDC). Only applications where evidence of REC and HRCDC approval is received by the RDGB will be recommended to the Central Statistics Office (CSO) for final approval on accessing the CSO RMF process.

Please indicate agreement to apply for ethical approval, provide detail on which institutional Research Ethics Committee(s) (RECs) you will seek ethical approval from. Also provide a likely data for receipt of this approval (DD/ MM/ YY format).

Please indicate agreement to apply for a consent declaration from the Health Research Consent Declaration Committee (HRCDC). Also provide a likely data for receipt of this approval (DD/ MM/ YY format).

**Note:** See HRCDC guidance on applying for a consent declaration and application form at <https://hrcdc.ie/apply/>. Please note a dedicated HRCDC application form has been developed to facilitate applying for a consent declaration for the purpose of processing RMFs from the COVID-19 Data Research Hub.

Section A: Applicant Details

1. Please provide details of the Lead Researcher(s)

The application must be made by the Lead Researcher who is seeking access to the COVID-19 Data Research Hub. The **Lead Researcher** **will serve as the primary point of contact for the RDGB during the application process.**

Access to the COVID-19 Data Research Hub is restricted to registered researchers from registered research organisations in Ireland. Applications from commercial organisations are not welcomed.

In order to expediate the RDGB application process for accessing the COVID-19 Data Research Hub the CSO will undertake the registration of research organisations and researchers in parallel to the RDGB application process. Applications received by the RDGB will only be scheduled for discussion at RDGB meetings following confirmation from the CSO that the registration process is confirmed or underway.

About CSO Researcher and Research Organisation Registration

The Lead Researcher must be employed by, or formally related to, a research organisation in Ireland that is already registered with the CSO, or that agrees to register with the CSO for the purpose of accessing RMFs before submitting this application.

Research organisation registration with the CSO establishes two roles:

* Senior Representative, i.e. someone with the authority to make commitments on behalf of the organisation, e.g. managing director, president, university chancellor or similar.
* RMF Contact, i.e. a person designated by the Senior Representative, who will be in charge of coordinating RMF project applications.

The term "Research Organisation" refers to organisations whose primary focus is on research and also to organisations who have research units where the organisation's principal activity is not research.

The Lead Researcher must also be registered or agree to register with the CSO If he/she has not previously accessed CSO RMF data on behalf of their current Research Organisation.

CSO Registration Forms for Research Organisations and for Researchers are available at: <https://www.cso.ie/en/aboutus/lgdp/csodatapolicies/dataforresearchers/forms/>

The Lead Researcher is asked to provide details on Name, Title, Position, research organisation, email address and telephone number.

The Lead Researcher is also asked to provide the address from where the COVID-19 Data Research Hub will be accessed (given that many researchers may be working remotely under COVID restrictions).

In accordance with CSO Governance safeguards. the CSO remote access service may be restricted based on the specified domain which must be a main fixed research organisation IP address. With the agreement of CSO, the researcher may connect remotely to this IP address via virtual private network (VPN). Please refer to your organisation’s IT Service Desk for confirmation of your device’s public IP address or organisation’s IP Range.

The Lead Researcher must also attach a short CV showing evidence of research achievements to his/ her application. A template and specific CV guidance notes are provided for this purpose. See: <https://www.hrb.ie/fileadmin/1._Non-plugin_related_files/HIE_files/2021_HIE/RDGB/RDGB_Lead_Researcher_CV_template.docx>

**Please note**: The application form must include the names and details of all researchers who will be involved in the proposed research project.

2. If the Lead Researcher is not the Principal Investigator for the research study, please give details

The Lead Researcher is asked to identify the Principal Investigator (PI) for the overall research study, if different from Lead Researcher who is seeking access to the COVID-19 Data Research Hub, and to provide details as above.

Please note that a CV is not required for the Principal Investigator (PI).

3. Please provide details of all other researchers involved in this research study

The Lead Researcher is asked to identify all other researchers named on the Application Form, and to provide details as above.

Please note that a CV is not required for other researchers beyond the Lead Researcher.

Note: All other named researchers on the Application Form must also be registered researchers from registered research organisations in Ireland. The above CSO registration process must all be applied for all named personnel.

4. Please provide details of the Research Organisation RMF contact to receive correspondence from the CSO in relation to this application, if different from Lead Researcher

The Lead Researcher is asked to identify the Research Organisation RMF contact, or proposed RMF contact if CSO registration process is being completed in parallel.

The CSO may correspond directly with the Research Organisation RMF contact in relation to the registration process.

Completed RDGB application forms must be countersigned by the RMF Contact, proposed RMF contact.

Section B- Research Project Details

1. RMF Details

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.

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 following COVID RMF(s) in the COVID-19 Data Research Hub are available for research purposes:

|  |  |
| --- | --- |
| Dataflow | Detail |
| a2I\_src – Swiftqueue | HSE Coronavirus Assessments, Test Referrals and Facilities data |
| C19HospitalCases\_src | Recorded Hospital Cases as a result of Covid-19 |
| CIDR\_src | HSE Computerised Infectious Disease Reporting SystemRegister of confirmed positive cases notified to Health Protection Surveillance Centre (HPSC) |
| HIPE\_src | Hospital Inpatient Discharge DataDetailed information with respect to admissions and discharges from the HIPE system |
| NOCA\_src | National Office of Clinical Audit Intensive Care Unit Data |
| SBAR\_src | Situation, Background, Assessment, Recommendation, Shift Handover Data |
| CCT\_src | COVID Care Tracker data The underlying C19 patient management system developed by the HSE system to manage the pandemic emergency |
|  | COVID-19 Vaccine Data |

New dataflows will be added to the COVID-19 Data Research Hub as they become available from the Health Services Executive (HSE). As with all researcher data, there is a time gap between data availability and the ability to share it given the stringent data protection protocols involved. The CSO also provides documentation describing the data to researchers which can take some time to prepare for new data sources.

The CSO has nominated a dedicated researcher liaison who can provide provisional advice to researchers on the available COVID-19 datasets and on the CSO safeguards and protocols in advance of submitting an RDGB application. It is strongly recommended that Lead Researcher contact the CSO in advance of making any application to discuss your data needs. Please contact:Sanela Smith, CSO Statistician email: Sanela.Smith@cso.ie

1.1 To which COVID RMF(s) in the COVID Data Hub are you requesting access?

Please specify the individual COVID RMF(s) for which you are seeking access.

**1.2 Please provide details of individual data sets and data variables:**

Please specify individual data sets and data variables in each data flow for which you are seeking access.

1.3 Please specify the data reference period (e.g. RMF name, quarter, year – please specify if you may require future releases of these RMFs which are not yet available):

For each of the individual COVID RMF(s) that you are seeking access please provide details of the data reference period including the RMF name, quarter and year. Specify if you may require future RMF releases which are not yet available.

**1.4 Please provide the clear rationale behind requesting access to the above data flows, data sets, data variables, and data reference period for your research project for this specific study in line with the principle of data minimisation.**

Please justify why you need access to specific dataflows, datasets and data variables and clearly explain if you understand and adhere to the principle of data minimisation.

1.5 What is the expected project duration (maximum being 12 months unless renewed)

Please indicate the expected length of the proposed access to the COVID-19 Data Research Hub in months (and the proposed start date).

Please note: It is the CSO who will grant final approval for access to the COVID-19 data using the robust protocols and safeguards. The researcher will be required to sign a Declaration of Secrecy and will then be appointed an Officers of Statistics for the purpose of their research project. CSO can only grant access a maximum of 12-month period in line with the one-year term of an Officer of Statistics term. If access to the COVID-19 Data Research Hub is required beyond this timeline the Officer of Statistics appointment will be renewed in accordance with CSO procedures.

2. Project Overview

2.1 Please provide details of the proposed research project including an outline of the main aims and objectives, methodology and deliverables of the proposed research.

You are asked to provide a summary of the proposed research including the objectives, design, expected outcomes and potential of the findings to answer policy and/or practice-relevant questions through the use of secondary data.

Demonstrate how the proposed research will build on existing research to influence the application of the research findings into the Irish healthcare system.

Sufficient detail, including the reason why access to each requested RMF is required, should be provided to allow an assessment of the proposal under the principle of data minimisation. The data provided to the researcher will be limited to those topics/ variables which are necessary to the specific research study.

2.2 Describe how the proposed research is relevant to COVID-19.

Explain why the research project is important and timely in a COVID-19 context. It is important to describe the current healthcare delivery context in Ireland when discussing issues around need, relevance, timeliness, and feasibility.

2.3 Describe the potential benefits of your research to public/patient/wider community. Have any consultations or engagements been undertaken with focus groups, advocacy groups, patient and/or representatives regarding your research?

Please provide details of where there has been public involvement in the preparation and/or design of the wider research project and/or provide details of proposed future public involvement. Provide information on the individuals/groups and the ways in which they will be involved. If you feel that this is not applicable to your application, you are asked to explain why.

2.4 Please provide details of any International partners and their role in the research?

Access to the COVID-19 Research Data Hub is restricted to registered researchers from registered research institutions in Ireland.

Provide details of any international partners and their role in the research study.

3. Statistical Disclosure Control

The processes for authorising access to Research Microdata Files (RMF) within the COVID-19 Data Research Hub and for managing RMF research projects are strictly controlled by the CSO.

The researchers undertaking the research study are/ will be appointed as Officers of Statistics by the CSO under Section 20(c) of the Statistics Act, 1993 and are legally obliged to ensure the confidentiality of RMF data. As part of this, the Lead Researcher applying for access to RMFs are required to demonstrate their knowledge of statistical disclosure control and to apply these methods to all tables intended for dissemination.

Any discussions of the data by the Lead Researcher (e.g. discussions of tables or analysis which could potentially disclose details of individual records) must be restricted to other Officers of Statistics appointed to the same research project. Analysis of RMFs will take place within the CSO Researcher Data Portal (RDP). 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). All researcher outputs are checked by a CSO statistician to ensure data confidentiality and compliance with the CSO Statistical Disclosure Control policy before emailing the approved output to the researcher

Please provide details of your experience and competency in relation to the application of statistical disclosure control (SDC). This includes:

* 3.1 Confirmation that you have read and understood the CSO Tabular SDC Guidance Document (available at: <https://www.cso.ie/en/aboutus/lgdp/csodatapolicies/dataforresearchers/resourcesforresearchers/>)
* 3.2 An outline of your understanding of Statistical Disclosure Control (SDC) including the criteria that he/ she will use to determine if aggregated tabular data is disclosive or not
* 3.3 Agreement to apply SDC Primary Suppression rules to all output as required
* 3.4 Agreement to apply SDC Secondary Suppression rules to all output as required

Please note: Specific rules for working with RMFs will be forwarded by the CSO once the application has received final CSO approval

4. RMF Access and Security

The processes for authorising access to COVID-19 Research Microdata Files (RMF) and for managing COVID-19 RMF research projects are strictly controlled by the CSO. The RDGB is an added safeguard to support governance and transparency of this process under the Data Protection Act.

The ultimate discretion regarding the provision of access to RMFs rests with the Director General of the CSO. Following approval granted, the researcher will access the specific COVID-19 datasets required for their research via the CSO Researcher Data Portal (RDP). The CSO technology in facilitating secure access to microdata is in keeping with best practice internationally. The RDP is a locked-down Citrix environment from which no data can be extracted without the approval of the CSO. The researcher logs on using a unique username, PIN and password – as well as this, the researcher’s access may be restricted to a specific IP address.

Access to RMFs is a privilege granted to researchers. Please provide details on the following issues related to access and security:

* 4.1 any other potential data sources for this proposed research, specifying any relevant data sources
* 4.2 why the research project requires access to RMF(s) rather than using aggregated data
* 4.3 any similar studies/ research projects been undertaken on this topic previously in Ireland
* 4.4 whether RMF access will, either directly or indirectly, provide any monetary gain to him/ her personally or to the organisation for whom he/ she works
* 4.5 any conflict of interest in accessing the COVID-19 RMFs by either the Lead Researcher, the organisation for whom he/ she works/ represent, or any other researchers or bodies that the Lead Researcher is collaborating with in respect of the research project
* 4.6 the physical security measures in place (e.g. location of the PC used, username and password, building security) to prevent unauthorised access to the RDP by any person who is not an Officer of Statistics:

5. Outputs

You (i.e. Lead Researcher) together with your research organisation have a duty to the public to ensure that discoveries and advancements in knowledge arising from access to the COVID-19 Data Research Hub are translated for public benefit.

Please provide details on the proposed outputs (e.g. reports, publications, presentations, articles, etc.) from your research and how these outputs will be disseminated, shared and made accessible during and after your research project.

In particular, you are asked to identify the target audience for the proposed outputs, to comment on whether the proposed research be released into the public domain, whether there will be a cost to cost to the public in accessing the results/outputs from the research.

Please Note: Once access to the COVID-19 Data Research Hub is approved by the CSO, specific rules applying to outputs/ publications will be shared. This will include a specific acknowledgement to include in all outputs, and clarification of responsibilities for ensuring the confidentiality of all outputs in line with the researcher appointment as an Officer of Statistics.

Please Note: It is expected that all researchers who are granted final CSO approval to access the COVID-19 data will be required to publish a Data Note on the HRB open publication platform, HRB Open Research ([www.hrbopenresearch.org](http://www.hrbopenresearch.org)), within one month of approval. Further details of HRB Open Research and the content of this Data Note will be shared directly with approved researchers.

6. Contractors/ Commissioners

Please confirm if you are undertaking the research on your own behalf (including that of your research organisation), or if you are contracted or commissioned to undertake this research of behalf of another party.

Please provide details of any relevant contracting or commissioning authority.

7. Funders/ Sponsors

It is important to understand the role of different organisations in supporting your research project.

Please give details of any Funding, or Funding organisation associated with this research project.

Provide details of any Sponsor involved in your research project. A Sponsor is an organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. It is a legal requirement for any clinical trial of an investigational medicinal product (CTIMP) to be sponsored. The sponsor is responsible for ensuring that a clinical trial complies with the legislation and Good Clinical Practice (GCP).

Section C- Declarations

You are asked to provide a signed declaration to confirm that you are duly authorised by your organisation to submit this application to the RDGB, and that the details provided in the application are, to the best of your knowledge, correct.

If your organisation is already registered with the CSO this declaration should be counter-signed by the research organisation RMF contact to confirm that you are employed by, or formally related to the research organisation and that the research will be conducted in accordance with the terms of the CSO Research Microdata Files policy.

If the Research Organisation registration process is being undertaken in parallel to this application, the proposed RMF contact from the registration process should countersign.

A supplement to Section C requires a similar declaration from the research organisation RMF contacts (or processed RMF contacts) for all other named researchers on the Application Form. Where there are researchers from multiple registered Research Organisation on this application, please duplicate this section to record all required signatures.

Please note: Any reference to signatures or dates in this section can be read as meaning the typed name and date where such an application is forwarded electronically.

11. Submission of Applications

**This is a rolling call for applications. The call will open on 3 March 2021.**

This Application Form must be completed by the Lead Researcher and submitted by email in .doc format to COVIDDatahub@hrb.ie. Section C, the declaration, must be countersigned by the Research Organisation’s RMF Contact (or proposed RMF contact).

***The Lead Researcher is responsible for driving the application process and it is the responsibility of the Lead Researcher to email all supporting documentation to the RDGB Secretariat at COVIDdatahub@hrb.ie. If the documentation is not received by the RDGB, in the correct format or is not properly signed or submitted, the application will be deemed ineligible without further review.***