Research Data Governance Board (RDGB)

Standard Operating Procedure

for accessing the COVID-19 Data Research Hub (Research Microdata Files)

Version 1.0

**Last updated:** 15 February 2021

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

**Contact:** COVIDdatahub@hrb.ie

1. Introduction
2. This document sets out the standard operating procedures (**SOPs**) under which the Research Data Governance Board (**RDGB**) facilitates access to the Research Microdata Files (**RMF**) within the Central Statistics Office (**CSO**) COVID-19 Data Research Hub.
3. As part of the national Covid-19 response, an agreement has been reached under Section 11 of the Statistics Act, 1993 between the CSO, the Department of Health, the Health Services Executive and others to support the collection, collation and statistical analysis of COVID 19 related data.
4. The Central Statistics Office (CSO) has been maintaining a COVID-19 Data Research Hub since April 2020. To date this COVID-19 data has been used solely by a sub-group of the National Public Health Emergency Team to conduct statistical analysis on healthcare data.
5. Now, in partnership with the CSO and the HRB, an application process has been put in place to enable registered researchers from registered research organisations to apply to access the COVID-19 data for research purposes. Applications are welcome from non-commercial entities.
6. A series of safeguards have been put in place to protect patient privacy under stringent and transparent rules while advancing our understanding of COVID-19 for the benefit of people’s health, patient care as well as health care policy and planning. Following a rigorous approval process, successful researchers will only have access to data from which all identifiers such as names and addresses will be removed.
7. The RDGB is an independent body established jointly by the Health Research Board (**HRB**) and the Central Statistics Office (**CSO**), in close collaboration with the Department of Health in Ireland. Members of the RDGB are appointed jointly by the HRB and the CSO. The RDGB act as a central point for application receipt, screening, review and prioritisation of data requests prior to accessing the CSO service.
8. 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 to its supported service to use the COVID-19 Data Research Hub.
* Noting that other regulatory approvals for the research projects are secured (Research Ethics approval; Consent Declarations from the Health Research Consent Declaration Committee (HRCDC));
* Monitoring the demand for and the use of the 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.
1. The Secretariat role is to administratively support the RDGB in all aspects of its work. It is provided by and located in the HRB.
2. This SOP sets out the procedures to be followed by the RDGB and the Secretariat in carrying out their respective functions.
3. Composition, functions and duration of the RDGB
4. The RDGB comprises six Board members plus one Chair.
5. A quorum consists of five members including the Chair.
6. The RDGB members have been jointly appointed by the HRB and the CSO based on their independent research expertise, knowledge and perspectives to help realise the full potential of the COVID-19 Data Research Hub and to ensure the best practice approach for the research community.
7. The RDGB shall meet once every month or as required until the end of duration or end of the ongoing COVID-19 national public health emergency.
8. From time to time co-opting of additional members with specific expertise in case of any emergencies or absences may be required.
9. The term of the RDGB will be initially set up as 18 months, or until when COVID-19 has been declared no longer a national public health emergency.
10. Members will attend meetings using video conferencing in the interest of public health, until a time in which it is deemed safe to meet in person.
11. Secretariat
12. The Secretariat will provide online guidance and support to the applicants, and information on the CSO approval of COVID-19 research proposals.
13. The Secretariat will perform any administration or management related duties including hosting RDGB meetings and informing decisions to the applicants and to the CSO including:
* Preparing and distributing the agenda and applications for the RDGB
* Upon receipt of an application issuing a tracking number
* Ahead of sharing applications with the RDGB, reviewing all submissions to ensure all applications are deemed valid, and sharing with CSO for its own preliminary review
* Scheduling applications for upcoming RDGB meetings
* Keeping a record of the meeting and its outcomes and sharing outcomes, and other supporting evidence required and supplied by the Applicant, with the CSO for its final approval.
* Preparing meeting minutes for approval.
1. Meeting procedures
2. Meetings of the RDGB will initially be held on a monthly basis.
3. For workflow management purposes, the Chair of the RDGB, in consultation with the Secretariat may, at his or her discretion, limit the number of applications to be reviewed at any given meeting.
4. The minutes of the meetings of the RDGB will be prepared by the Secretariat in consultation with the Chair, and will be submitted to the following meeting of the RDGB for approval.
5. A summary list of research activity granted final CSO approval to access to the COVID-19 Data Research Hub will be published on the RDGB webpage.
6. Decision Making Process
7. The RDGB will endeavour to reach decisions by consensus. If consensus cannot be reached, the Chair will decide the course of action to derive a decision.
8. The RDGB may make one of the following decisions:
	* 1. Recommended. The applicant is required to accept the approval within a specified number of days, and he or she will then be forwarded to the CSO for its final approval decision. Note: applicants must also have sought and obtained ethical approval and a consent declaration from the HRCDC before any recommendation is made to the CSO.
		2. Provisionally recommended, subject to revision required to the proposal or questions posed to the applicant. The applicant will have a specified number of days to respond to the RDGB queries. Any revisions or answers must be submitted to the RDGB to support consideration for final recommendation.
		3. Not recommended, the reasons for not recommendation should be forwarded to the applicant. The Applicant should confirm receipt of the outcome. Any intended resubmission of a declined application should be first discussed with the Secretariat.
9. The final decision of RDGB will be communicated to the applicants in writing following the RDGB meeting. All decisions taken will be recorded in the meeting minutes.
10. Application
	1. Application Requirements and Review Process
11. The Secretariat will provide detailed guidance with respect to correctly completing the RDGB Application Form and with clarification of the steps that must be undertaken by applicants prior to the submission of an application.
12. Where possible, answers to commonly asked queries will be provided via a dedicated online Frequently Asked Questions (FAQ) section which will be updated regularly.

All queries to the Secretariat must be submitted in writing to COVIDdatahub@hrb.ie . Further information can be found at [www.hrb.ie](http://www.hrb.ie)

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 Jojkic, CSO Statistician email: c19researchinfo@cso.ie

1. If necessary, and where appropriate, advice to Applicants from the RDGB Secretariat may be provided in writing (by email), by phone or in person, depending on the nature of advice given.
2. Applications may be submitted by non-commercial entities based in Ireland seeking to access the COVID-19-Data Research Hub for the purposes of health research.
3. The RDGB will require that:
* The application is submitted on the prescribed application form, electronically to the RDGB Secretariat COVIDdatahub@hrb.ie. Application forms can be downloaded at: <https://www.hrb.ie/fileadmin/1._Non-plugin_related_files/HIE_files/2021_HIE/RDGB/RDGB_Application_Form.docx>
* Following an initial check by the Secretariat, the application will be referred onwards to the CSO to consider preliminary approval for specific CSO requirements for accessing and use of the COVID-19 Data Research Hub.
* Following this stage, applicants will be informed on whether application will be progressed, and the timing of RDGB meeting at which it will be discussed.
1. If an application is deemed invalid, the Secretariat will notify the applicant.
2. An application will be regarded as valid if it meets the following criteria:
* Applications are within scope for review by the RDGB and meet the criterion for being directly related to COVID-19;
* The application form has been completed with all questions sufficiently and comprehensively answered;
* A short curriculum vitae (template provided) for the Lead Researcher has been submitted;
* The application form has been signed by the Lead Researcher and by a Research Organisation RMF contact (or proposed RMF contact);
* The Applicants Research Organisation must already be registered or agree to register with the Central Statistics Office for the purpose of accessing RMFs.
For further information and an application form see: <https://www.cso.ie/en/aboutus/lgdp/csodatapolicies/dataforresearchers/forms/> ;
* The Applicant and all other 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/ she has not previously been appointed as a Central Statistics Office (CSO) Officer of Statistics he/ she must complete a separate Researcher Registration Application Form: <https://www.cso.ie/en/aboutus/lgdp/csodatapolicies/dataforresearchers/forms/>;
* The Applicant undertakes to seek and obtain ethical approval from an Institutional Research Ethics Committee (REC);
* The Applicant undertakes to seek and obtain a consent declaration from the Health Research Consent Declaration Committee (HRCDC). 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 Data Hub.
1. The opinion of the Chair of the RDGB will be sought where there is any doubt that an application is within scope for review by the RDGB.
2. 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 Patricia Clarke

**HRB Project Officer:** Dr Sharon Kappala

Appendix 1

Definition of Health Research

“health research” means any of the following scientific research for the purpose of human health:

* + 1. research with the goal of understanding normal and abnormal functioning, at molecular, cellular, organ system and whole-body levels;
		2. research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury;
		3. research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals;
		4. research with the goal of improving the efficiency and effectiveness of health professionals and the health care system;
		5. research with the goal of improving the health of the population as a whole or any part of
		the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status.

Health research referred to in clause (i) to (v) above may include action taken to establish whether an individual may be suitable for inclusion in the research.

Appendix 2

Research Data Governance Board (RDGB)

Terms of Reference

Scope

1. The Research Data Governance Board (RDGB) acts as a central point for application receipt, screening, review and prioritisation of data requests prior to accessing the Central Statistics Office (CSO) service which will facilitate secure and controlled access to data in the COVID-19 Data Hub.
2. The data available to researchers will be limited to datasets provided to the CSO in the context of the Ministerial release letter for COVID-19 analysis.
3. The RDGB will consider research that is defined as health research according to the Health Research Regulations 2018 (Regulation 3(2)(a)). <http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf> .
All research should be compatible with statistical use and confidentiality requirements from the Statistics Act, 1993.
4. The RDGB will determine if a research study or proposal is related to the Covid19 pandemic, and therefore eligible to apply to the Central Statistics Office for access to relevant COVID-19 health data.
5. The RDGB will ensure consistency of decisions in relation to projects, researchers, and data or ethical standards.
6. As needed, the RDGB may be asked to consider the scale and feasibility of applications versus the value of the research.
7. The RDGB will require evidence of approval from both a Research Ethics Committees (REC) and from the Health Research Consent Declaration Committee (HRCDC) when making its final recommendation.
8. The RDGB will provide this recommendation to the Central Statistics Office.
9. The RDGB will assist in the identification of new data sources of potentially high value for research purposes.

Membership

One Chair plus six members.

Term

The RDGB’s term will be 18 months, or when COVID-19 has been declared no longer a national public health emergency, whichever comes first.

Secretariat

Health Research Board

Appendix 3

Research Data Governance Board (RDGB)

Membership Details

| Name  | Organisation | RDGB Role |
| --- | --- | --- |
| **Prof Patricia Kearney** | University College Cork | Chair |
| **Prof Catherine Comiskey** | Trinity College Dublin | Member  |
| **Dr John B. Howard** | University College Dublin | Member |
| **Dr Frank Moriarty** | Royal College of Surgeons in Ireland | Member |
| **Ms Rosalyn (Ros) Moran** | EKOS Social and Environmental Research Associates | Member |
| **Dr Anne Nolan** | The Economic and Social Research Institute | Member  |
| **Dr Akke Vellinga** | National University of Ireland Galway | Member |