

**CONSENT DECLARATION APPLICATION FORM**

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**To process or further process[[1]](#footnote-2) personal data for the purposes of the health research study.**

**PLEASE NOTE**

* Detailed guidance on the application process to access the Central Statistics Office Health Research Data Centre (CSO Health RDC) can be viewed on the Central Statistics Website (CSO) website and by contacting the HealthRDC@cso.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)
* 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 also reference the Assisted decision-making act and amendment. [ADMA 2015](https://www.irishstatutebook.ie/eli/2015/act/64/enacted/en/html), [ADMA as amended 2022](https://www.irishstatutebook.ie/eli/2022/act/46/enacted/en/html).
* 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 the** **data controller’s Data Protection Officer prior to submission.**

Owner: Secretariat, HRCDC

Reviewed also by CSO

Contact: Secretariat@hrcdc.ie

**PLEASE ENSURE THE FOLLOWING DOCUMENTATION IS PROVIDED.**

**List of Documents needed:**

[ ] Ethics Approval document *(Note: a copy of the REC application form is not required).*

[ ]  Data Protection Impact Assessment (DPIA)

[ ]  Evidence of the Data Controller’s\* DPO(s) review of the DPIA.

[ ]  Participant Information Leaflet, consent / assent forms (if applicable)

[ ]  Copy/links to other transparency measures (if applicable)

[ ]  RDGB approval / conditional approval, if available

[ ] Signatures of all Data Controller(s)\*

***(Note: Data controller(s) above refers to the data controller of the research study that is seeking the consent declaration. DPO feedback/signatures from an Irish research site (e.g., a hospital) is not sufficient if that site is not a data controller of the research study in question)***

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| Appendix II has 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 Health Research Data Centre.(Health RDC) In signing this application, you are confirming that you agree to comply with the Health RDC requirements.  All other sections need to be completed by the applicant.  |

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 Health RDC only, and *no other personal data[[2]](#footnote-3)*.

[ ]  The Applicant has received confirmation from the Research Data Governance Board[[3]](#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 Health RDC

[ ] The researcher(s) directly involved with the research study accessing the Health RDC 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.

**TITLE OF RESEARCH:**

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| **Please 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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**THE PUBLIC INTEREST CASE:**

*Regulation 5(4)(e)*

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| 1. **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 A: APPLICANT DETAILS**

*Regulation 5(4)(b)*

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| **Data Controller name and contact details** (Art 4/GDPR) The Data Controller determines how and why personal data is being collected and used (processed) for this health research study. (i.e. study data) 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:Organisation Address: Email: Telephone: [ ]  Data Controller |

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| 1. **Lead contact person to receive correspondence in relation to this application, if different from Section 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** (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** (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** (Art 28/GDPR)

A Data Processor acts on the instruction of the Data Controller or another data processor (in a subcontracting relationship for example). Include any sub-contractors, service providers, academic institutions carrying out testing/analysis, data processing on the instruction of either the Data Controller or data processor, for this study.  |
| [ ]  Not applicable Name of organisation:Name of lead contact:Address/website: Principle business:Role undertaken by Processor in research study: |
| 1. **Controller-Processors: Please outline what legal agreements, contracts or legal acts are in place between the Controller(s) and Processor**(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 and/or 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 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.[ ]  If provisional REC approval in place, please provide a copy of Applicant responses to queries raised by the REC(s) This information is **not necessary** if full REC approval is in place. Repeat above details if there are multiple REC approvals for multi-site data processing |

**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 and its expected outcomes.**

**(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, participant inclusion and exclusion criteria, consent process.  |
| [ ]  Appendix I completed. Please note it is not necessary to provide the full study protocol  |

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

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| 1. **i)** **Please list/describe the personal data which will be obtained and used for the research (Art 4, 9 GDPR)** eg names, date of birth, age, gender, clinical data (if so, what kind), addresses, economic data (if so what kind), ethnicity
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| 1. **List the data sources to be used in the research, for example, TILDA, PRCS etc.**
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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 / merging the personal data from this study with different /external sources of information, please describe what is involved, other parties involved and the purpose of this merging. Please detail the safeguards that will be in place to protect the participants personal data, in this instance.**
 |
| 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 Details:  |

**PART C: CONSENT**

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| **It is recognised that it is not possible for the researchers in this application to obtain consent as they do have access to the contact details of the individuals included in the CSO Health RDC. Also, given the large quantity of data from different individuals included in data centre, it is also not feasible to obtain consent for this large number of participants.**  |

**PART D: 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 and Art 9 GDPR)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 E: INFORMATION REQUIREMENTS, DATA SECURITY ARRANGEMENTS AND TRAINING**

*Regulation 3(1)(d)*

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| 1. **Transparency is an important data safeguard especially when explicit consent cannot be obtained. Specify the arrangements that are or will be in place to ensure that personal data from this study are processed in a transparent manner and that any information in relation to the study is easily accessible and easy to understand to participants and/or the public. (Art 5 GDPR)**. 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)*

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

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| 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**
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| 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),*

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| 1. **i) Data Protection Impact Assessment**

Please attach a copy of the DPIA, which has been reviewed by the data controller (s) Where there are joint data controllers, a single DPIA will suffice, but the review of each joint data controller’s DPO needs to be included:  |
| [ ]  Copy of DPIA attached. |
| **ii) Please outline/attach the advice of the Data Controller’s Data Protection Officer(s) (DPO) regarding the data protection risks of the research study.** Please outline any specific risks highlighted by the DPO below, and the advice provided to mitigate these risks. |

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| **Name of DPO #1:**[ ] Advice of DPO#1:**Name of DPO #2:**[ ] Advice of DPO#2: |

**SIGNATURE PAGE TO FOLLOW**

**PART G: Signatures of behalf of the data controller(s) of the study are required**

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 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:Please provide an acknowledgement that this application form has been reviewed 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: |

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| **Signature of Applicant/Principal Investigator (if not a data controller)** |
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| Name: Title: signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:Read and acknowledged by an authorised representative within the Organisation: [this must be an appropriate and competent authority eg Data Protection Officer, Legal counsel] |

DATA CONTROLLER #2 (if joint controllers)

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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 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: |

**APPENDIX - I**

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| **PART B, Section 3: Design & Methodology of Research (Max 2 Pages)** **Please note it is not necessary to include the full text of the study protocol.**  |
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**APPENDIX – II**

**Standard conditions and procedures that apply when accessing data through the CSO Health Research Data Center (CSO Health RDC) .**

* Research Microdata files (RMFs) will not leave the CSO Health RDC. Researchers accessing the Health RDC 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. Data will not be shared with any third party, other than those detailed in the HRCDC application.
* Processing of the data will only take place in Ireland. Research Microdata files (RMFs) will not leave the Health RDC as outlined above. Only registered researchers from recognised research Institutions in Ireland are permitted to apply for access to these data.
* In relation to data sources; The CSO takes multiple data flows from the HSE and other government departments. 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. Only designated Officers of Statistics can access the RMFs.
* 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 is applied to remove personal data such as patient's name, address, date of birth and contact details.
* All arrangements between the Data Controller of the research study and Data Controller (CSO) of the Health RDC are set out on the CSO ‘RMF Applications Procedure’ webpage. 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.
* Data processing activities carried out during the research: Researchers will access pseudonymised RMFs as permitted by the CSO. Analysis of RMFs within the portal of the Health RDC, 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.
* If anonymised data could sufficiently address research needs, there would not be a requirement for RMF access to Health RDC. 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. RMFs are not published or made available to the general public.
* Safeguards; 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; . 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 minimised at the output-checking stage of the process.
* Exit strategy; 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 Health RDC is terminated.
* Data security arrangements:
	+ 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 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.
	+ 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.
	+ 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.
	+ 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.
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-2)
2. Where personal data from other sources (other than Health RDC) 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: insert link [↑](#footnote-ref-3)
3. The RDGB is an independent body, for further information please contact HealthRDC@cso.ie [↑](#footnote-ref-4)