Secretariat triage list to ensure **validity** of Applications

-

|  |  |
| --- | --- |
| **Application Ref:** | Next number sequence on worksheet |
| **Application Title:** | Title of research on application  |
| **Applicant Organisation (Data Controller(s)):** | Part A: Applicant Details 1. Address not required |
| **Lead Applicant:** | Part A – Applicant Details 2 |
| **Research Objective:** | Lay Summary of Research  |
| **Reason for seeking a Declaration:** | Part B, Section 5 & Part C, Section 1 [• *FOR CSO APPLICATIONS* *DELETE AS REQUIRED* The Applicant is seeking to access and obtained pseudonymised data (research microdata files) from the COVID-19 Data Research Hub, hosted by the Central Statistics Office. As the data being accessed is pseudonymised data and that it is not feasible to seek consent from individuals whose data is held by the CSO within the COVID-19 data hub, a consent declaration is required.]  |
| **Duration of Declaration**  | Part B, Section 1& 11– Nature of health research and personal data being used [• *FOR CSO APPLICATIONS DELETE/AMEND AS REQUIRED* The consent declaration is requested for one year in line with the duration of the Officer of Statistics appointment made to the Applicant] |
| **REC Approval Date**  | Found on the attached Rec Approval letter |
| **RDGB Approval status** | [•Research Data Governance Board approval/conditional approval has been granted for eligibility and recommendation to access COVID19 Data Research Hub]*OR* [•The Applicant has received confirmation from the Research Data Governance Board (RDGB) Secretariat, that a validated RDGB application has been scheduled for RDGB review]  [*DELETE THIS ENTIRE SECTION, OR CHOOSE OPTION ABOVE AS APPROPRIATE*]  |

|  |
| --- |
| [ ]  Application Form 1. **’New research**’ project: Commencing on/after Aug 8th, 2018. - USE THIS OPTION FOR NEW APPLICATION[ ]  Application Form 2. **’Current research**’ project: Commenced before Aug 8th, 2018, where the existing consent was initially considered compliant under previous data protection law (Regulation 6(4)(b)), but following the Amendments (2021) and after consideration by the Applicant, the consent was not fully compliant. |

|  |
| --- |
| **Points to note for ease of review of applications: THIS SECTION IS USED FOR NOTES OF THE SECRETARIAT FOR THE HRCDC. IT can be used to highlight websites, or information in substantiating documents, but not necessarily highlighted in the Application form.** PART A: **where is this information found** PART B:PART C:PART D:PART E: PART F: |

|  |
| --- |
| **The following observations have been made by the Secretariat regarding potential conditions/recommendations as enhanced safeguards, if a consent declaration was favorable:** |

**APPLICANT DETAILS**

[ ] The Data Controller(s) and Joint-Controller is specified[[1]](#footnote-1) Part A: Applicant Details 1

[ ] Data Processor(s) are specified[[2]](#footnote-2) Part A: Applicant Details 6

[ ] Specify arrangements/contract/agreements in place with controller(s)/Processors Part A: Applicant details 7

[ ] Funders/Sponsors are specified[[3]](#footnote-3) Part A Applicant Details 8

[ ] Research units have been identified

[ ]  check the estimated number of participants to be recruited in Ireland

[ ] Any person (other than a joint data controller or data processor) with whom it is intended to share any of the personal data obtained or further processed (including where it has been pseudonymised or anonymised)[[4]](#footnote-4) Part A Applicant Details 9

[ ] Jurisdiction of processing addressed Part A Applicant Details 10

[ ] Ethics Approval has been granted[[5]](#footnote-5) **-**  **(Folder X, Doc Y)**

[ ] Research Data Governance Board approval status completed/copy of outcome letter has been provided. Delete if not a CSO application

**NATURE OF HEALTH RESEARCH & PERSONAL DATA**

[ ] Nature and Use of data being processed Part B, 2

[ ] The duration of the data processing/use of data, with start and end points Part B, 1

[ ] Appendix I is completed; Design & Methodology Found at bottom of application (Part B, 3)

[ ] Evidence that the data use is restricted to those processing the data for research Part B, 4i)

[ ] Evidence that anonymization of data is not possible[[6]](#footnote-6) Part B, 6

[ ] Evidence that data processing will not damage/distress the data subject[[7]](#footnote-7) Part B, 7

[ ] Evidence of data minimisation[[8]](#footnote-8) Part B, 8

[ ] There will be no disclosure of personal data unless required by law or subject has given his or her explicit consent to the disclosure[[9]](#footnote-9) Part B, 9

[ ] Reference any data linkages[[10]](#footnote-10) Part B, 10

[ ] Exit strategy where no declaration shall be required Part B, 11

**CONSENT**

[ ] Rationale for non-consent[[11]](#footnote-11) **Part C, 1**

[ ] Evidence of public/patient engagement or consultations (the research objectives/ feasibility of obtaining consent)[[12]](#footnote-12) Part C, 3

[ ] This section is adequately addressed if participants lack decision-making capacity Part C, 4

**THE PUBLIC INTEREST CASE**

[ ] Statement that the Public Interest outweighs the requirement for explicit consent[[13]](#footnote-13) Part D

**LEGAL BASIS FOR THE PROCESSING OF PERSONAL DATA**

[ ] Applicant meets one of the legal basis under Article 6[[14]](#footnote-14) Part E

[ ] Applicant meets one of the conditions under Article 9(2)[[15]](#footnote-15) Part E

**INFORMATION REQUIREMENTS, DATA SECURITY ARRANGEMENTS & TRAINING**

[ ] Evidence of transparency arrangements[[16]](#footnote-16) Part F, 1

[ ] Evidence of controls in place to limit and log access to the data[[17]](#footnote-17) Part F, 2ii

[ ] Measures to protect the security of the personal data concerned[[18]](#footnote-18) Part F, 2iii

[ ] Arrangements to anonymise, archive or destroy personal data[[19]](#footnote-19) Part F, 2iv

[ ] Other technical and organisational measures designed to ensure that processing is carried out in accordance with the Data Protection Regulation[[20]](#footnote-20) Part F, 2v

[ ] Data protection law training has been completed by the health researchers[[21]](#footnote-21) Part F, 3

[ ] A Data Protection Impact Assessment (DPIA) has been completed[[22]](#footnote-22) **- (Folder X, Doc Y)**

[ ] The Data Controller’s DPO(s) has been consulted[[23]](#footnote-23) **- (Folder X, Doc Y)**

**SIGNATURES - DATA CONTROLLER(S)**

 [ ] Signature of Applicant (Data Controller Part A, 1)

 [ ] Signature of Co-Applicant

**OTHER: AS REQUESTED BY SECRETARIAT**

[ ] Evidence of Patient Information Leaflet/Consent Forms **- (Folder X, Doc Y)**

[ ] Data Protection Policies & transparency notices or equivalent **- (Folder X, Doc Y)**

[ ] Contractual arrangements between data controllers/**- (Folder X, Doc Y)**

[ ] Pre-submission advice **- (Folder X, Doc Y)**

1. Regulation 5(4)(b) [↑](#footnote-ref-1)
2. Regulation 3(1)(b)(iv) [↑](#footnote-ref-2)
3. Regulation 3(1)(b)(v) [↑](#footnote-ref-3)
4. Regulation 3(1)(b)(vi) [↑](#footnote-ref-4)
5. Regulation 5(4)(c)(vii) [↑](#footnote-ref-5)
6. Regulation 5(4)(c)(i) [↑](#footnote-ref-6)
7. Regulation 5(4)(c)(ii) [↑](#footnote-ref-7)
8. Regulation 3(1)(c)(iii) and Regulation 5(4)(c)(iii) [↑](#footnote-ref-8)
9. Regulation 5(4)(c)(iv) [↑](#footnote-ref-9)
10. Regulation 5(4)(d) [↑](#footnote-ref-10)
11. Regulation 5(4)(e) [↑](#footnote-ref-11)
12. Regulation 5(4)(d) [↑](#footnote-ref-12)
13. Regulation 5(4)(e) [↑](#footnote-ref-13)
14. Regulation 5(4)(a)(i) [↑](#footnote-ref-14)
15. Regulation 5(4)(a)(ii) [↑](#footnote-ref-15)
16. Regulation 3(1)(d) [↑](#footnote-ref-16)
17. Regulation 3(1)(c)(iv) and Regulation 3(1)(c)(v) [↑](#footnote-ref-17)
18. Regulation 3(1)(c)(vi) [↑](#footnote-ref-18)
19. Regulation 3(1)(c)(vii) [↑](#footnote-ref-19)
20. Regulation 3(1)(c)(viii) [↑](#footnote-ref-20)
21. Regulation 3(1)(b)(vii) [↑](#footnote-ref-21)
22. Regulation 5(4)(d) [↑](#footnote-ref-22)
23. Regulation 5(4)(c)(vi) [↑](#footnote-ref-23)