

**CONSENT DECLARATION APPLICATION FORM**

**-**

**To process or further process[[1]](#footnote-1) personal data for the purposes of health research commencing on or after 8 August 2018**

**PLEASE NOTE**

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

Version 4.2

Date: January 2023

Owner: Secretariat, HRCDC

Contact: [Secretariat@hrcdc.ie](mailto:Secretariat@hrcdc.ie)

**TITLE OF RESEARCH:**

|  |
| --- |
| **Please provide a short title for the research Study** |
|  |

**LAY SUMMARY OF RESEARCH:**

|  |
| --- |
| 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. |
|  |

**PART A: APPLICANT DETAILS**

*Regulation 5(4)(b)*

|  |
| --- |
| **Lead Data Controller name and contact details** ([Ref Art 4/GDPR](https://gdpr-info.eu/art-4-gdpr/))The Data Controller determines how and why personal data is being collected and used (processed) for the health research study. Please include the principal business of the Data Controllereg 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: |

|  |
| --- |
| 1. **Applicant/Principal Investigator name and contact details**   If the Applicant is the Data Controller, solely in their personal capacity, this should be made clear, and information provided to support that view.  eg sole trader, individual with private practice, not an employee of an organisation*.* |
| Name:  Address:  Email:  Telephone:  Data Controller |

|  |
| --- |
| 1. **Lead contact person to receive correspondence in relation to this application, if different from Section 2** |
| As Above:Name:Address:Email:Telephone: |

*Regulation 5(4)(b)*

|  |
| --- |
| 1. **Joint Data-Controller(s) name and contact details** ([Ref Art 26/GDPR](https://gdpr-info.eu/art-26-gdpr/))   e.g. consider co-investigators, collaborators etc and others that may also be determining how and why personal data is being used (processed) for the study. |
| Not applicableName 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)*

|  |
| --- |
| 1. **Joint Data-Controller(s): Please outline what arrangements are in place between the Joint Data-Controllers to reflect the roles and responsibilities** ([Ref Art 26/GDPR](https://gdpr-info.eu/art-26-gdpr/))   Example arrangements maybe data transfer agreements, inter-institutional agreements, contractual arrangements etc |
| Not applicable Details: |

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

|  |
| --- |
| 1. **Data Processors(s) name and contact details** ([Ref Art 28/GDPR](https://gdpr-info.eu/art-28-gdpr/))   A Data Processor acts on the instruction of the Data Controller. e.g. consider sub-contractors, service providers, academic institutions carrying out testing/analysis on the instruction of the Data Controller. |
| Not applicableName 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 or legal acts are in place between the Controller(s) and Processor** ([Ref Art 28/GDPR](https://gdpr-info.eu/art-28-gdpr/)) |
| Not applicable Other details: |

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

|  |
| --- |
| 1. **Please specify any Sponsor and/or funder(s) for the research study** |
| Not applicableName of organisation:Name of lead contact:Address/website:Principle business: Role undertaken by Sponsor/funder in research study: |

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

|  |
| --- |
| 1. **Please specify any third party (other than a joint data controller or data processor) with whom it is intended to share any of the data obtained (including where it has been pseudonymised or anonymised) and the purpose of such sharing.** |
| Not applicableName of Organisation:Principle Business: Purpose of Sharing:  Jurisdiction:  Details of data being shared: |

|  |
| --- |
| 1. **Jurisdiction of data processing for the research**   (Ref: <https://www.dataprotection.ie/en/organisations/international-transfers>, [Ref Chapter V/GDPR](https://gdpr-info.eu/chapter-5/)*)* |
| 1. Is it proposed to process any personal data outside of the State?   Yes  No   1. If Yes, please specify the recipient countries.   Non-EEA  EEA   1. If Non-EEA please identify the legal basis for the transfer of personal data below:   on the basis of an Adequacy Decision,  using the safeguard of Standard Data Protection clauses,  using the safeguard of Binding Corporate Rules,  on the basis of approved Codes of Conduct,  on the basis of approved Certification Mechanisms,  on the basis of a legally binding and enforceable instrument between public authorities or bodies,  on the basis of a Derogation   1. If a legal basis for transfer of personal data outside the EEA has been identified in iii) above, please name the country(ies) of transfer and outline what arrangements are in place governing the transfer: |

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

|  |
| --- |
| 1. **Please list all Research Ethics Committees (RECs) involved in approval of the research and attach a copy of outcome letter from each REC**   NOTE: The HRCDC cannot consider applications if REC approval, or provisional approval, is not in place. |
| Name of REC:  Date of REC approval (or provisional approval):  Copy of REC approval(s) attached  Confirmation that the REC approval specifically covers the health research study outlined in this application form  Copy of Applicant responses to queries raised by the REC(s)  NOTE: Where the Applicant has received provisional approval from a REC and has responded to and addressed queries raised, please attach these responses when submitting the application.  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**

|  |
| --- |
| 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. |
|  |

|  |
| --- |
| 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*.* |
|  |

|  |
| --- |
| 1. **Provide an overview of the proposed design and methodology of the research**   **(Max 2 Pages)**  Please complete Appendix I of this application form. Provide non-confidential information if possible. Do not use overly technical language or commercially sensitive information. Please include details of the number of anticipated participants in the research study. |
| Appendix I completed |

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

|  |
| --- |
| 1. **i)** **Describe the personal data which will be obtained and used for the research** ([Ref Art 4/GDPR](https://gdpr-info.eu/art-4-gdpr/), [Ref Art 9/GDPR](https://gdpr-info.eu/art-9-gdpr/))   eg names, date of birth, age, gender, clinical data, phenotype data, addresses, economic data, ethnicity |
|  |
| **ii) Identify the data sources from which the personal data will be obtained**  e.g. Medical records, General Practice records, Hospitals, Health Service providers, registries, databases, questionnaires, social media etc. |
|  |
| **iii)** **Outline what engagement has occurred, general or specific, with the Data Controller of the data sources on the likelihood that they will provide the personal data should a consent declaration be made** |
|  |
| **iv) If relevant, outline what arrangements will be in place between the Lead Data Controller of the research study and the Data Controller of the personal data**  eg data and material transfer/sharing agreement, memorandum of understanding, terms of use etc |
|  |

|  |
| --- |
| 1. **i)** **Describe the data processing activities that will be carried out during the life cycle of the research. A simple data flow diagram should be provided if possible** ([Ref Art 4(2)/GDPR](https://gdpr-info.eu/art-4-gdpr/))   Consider activities such as: accessing, collecting, recording, storing, adapting, pseudonymisation, anonymisation, analysis, linking, combining, sharing, transfers, archiving and destruction. |
|  |
| **ii)** **Will the research study involve genomic and/or genetic data generation, analysis and further processing?**  Genetic data is considered personal data in accordance with the GDPR ([Recital 34](https://gdpr-info.eu/recitals/no-34/)) the European Data Protection Board ([EDPB response/Section 51](https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf)). |
| Not applicable  Details of the nature of the genomic/genetic data analysis, processing and additional safeguards: |
| **iii)** **To establish why a consent declaration being sought, please outline what specific data processing activities will be carried out, without the explicit consent of the research participants** |
| As above  Specifically: |

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

|  |
| --- |
| 1. **Explain why the research requires that personal data be obtained and processed rather than fully, irrevocably anonymised data** ([Ref Recital 26/GDPR](https://gdpr-info.eu/recitals/no-26/))   NOTE: pseudonymised or de-identified data may also be considered personal data |
|  |

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

|  |
| --- |
| 1. **Describe how you will ensure that personal data will not be processed in such a way that damage or distress is, or is likely to be, caused to the participant** |
|  |

*Regulation 3(1)(c)(iii)*

|  |
| --- |
| 1. **Describe how you will ensure that only the minimal amount of personal data will be collected and used, and the personal data will go no further than is necessary for the purpose of attaining the research objective** ([Ref Art 5(1)(c)/GDPR](https://gdpr-info.eu/art-5-gdpr/))   This question relates specifically to the data minimisation principle. |
|  |

*Regulation 5(4)(c)(iv)*

|  |
| --- |
| 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** |
|  |

*Regulation 5(4)(d)*

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

|  |
| --- |
| 1. **Describe your exit strategy whereby the research study will no longer require a consent declaration**   Consider at what stage during the research study personal data will be rendered irrevocably anonymised to the Data Controller(s), returned or destroyed, or when future consent may be obtained etc. Where relevant, consider at what point the master list/key that codifies the personal data, will be destroyed. If a consent declaration is required over several years, or indefinitely, please set out the reasons why*.* |
|  |

**PART C: CONSENT**

*Regulation 5(4)(e)*

|  |
| --- |
| 1. **Why is it not possible to seek consent from the research participant(s) to process their personal data for this research study?**   Please substantiate the rationale with supporting evidence where possible. Consider the HRCDC guidance notes. If consent is not possible to obtain due to a lack of decision-making capacity, please complete Part C, Section 4 if applicable. |
|  |

|  |
| --- |
| 1. **In what way was consent from the participant(s) formally considered at the design stage or any stage of the research?**   eg was consent discussed with a research ethics committee, subject matter experts, collaborators, participant representatives or advocacy groups? Please substantiate the rationale with supporting evidence where possible. |
|  |

*Regulation 5(4)(d), as amended under S.I.18 of 2021*

|  |
| --- |
| 1. **What Public, Patient and Carer involvement activity (PPI) has been or, will be undertaken with focus groups, advocacy groups, patient and/or representative participants** **regarding:**   NOTE: PPI activity is considered an important data protection safeguarding activity, to gain representative perspectives and opinions where participants themselves cannot provide explicit consent. PPI activity also provides a valuable and meaningful way of seeking views on the support for and development of the research. This PPI engagement can further inform what transparency measures can be implemented and how, which itself is an important data protection principle. |
| 1. **the feasibility of obtaining consent:**   None, explain why: |
| 1. **support for, and development of the research:**   None, explain why: |
| 1. **other comments:** |

|  |
| --- |
| 1. **i) Briefly outline how the decision-making capacity of a research participant(s) is determined** |
| Not applicable  Brief outline of protocol: |
| **ii) Where proxy assent is being used as a suitable safeguard, briefly outline what measures are in place to ensure that the identified proxy is the most appropriate individual who can communicate on behalf of the participant and understands their will and preferences**  NOTE: proxy (next-of-kin relative, friend, as appropriate) assent for data processing on behalf of an individual that lacks decision making capacity has no lawful basis. However, proxy assent should be used as a suitable safeguard, in additional to seeking a consent declaration. Please provide study information leaflets and associated assent forms, and other relevant documentation as relevant. |
| Not applicable  Brief statement: |

|  |
| --- |
| 1. **Will consent from the participant(s) be sought at any stage during the research study?**   If deferred consent/consent-to-continue is being obtained, please expand further. This answer will tie in with Part B, Section 11, exit strategy. Provide proposed study information leaflets and assent form, deferred consent forms and other relevant documentation as relevant. |
|  |

|  |
| --- |
| 1. **Withdrawal of consent and/or assent: What will happen to the personal data if the participant does not provide deferred consent, or proxy assent is not provided or is withdrawn**   If there are specific protocols for managing the withdrawal of consent and assent, please outline in detail. |
|  |

**PART D: THE PUBLIC INTEREST CASE**

*Regulation 5(4)(e)*

|  |
| --- |
| **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. |
|  |

**PART E: LEGAL BASIS FOR THE PROCESSING OF PERSONAL DATA**

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

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

**PART F: INFORMATION REQUIREMENTS, DATA SECURITY ARRANGEMENTS AND TRAINING**

*Regulation 3(1)(d)*

|  |
| --- |
| 1. **Specify the transparency arrangements that are/will be in place to ensure that personal data are processed in a transparent manner** ([Ref Art 5(1)(a)/GDPR](https://gdpr-info.eu/art-5-gdpr/))   Transparency is an important data protection principle, especially in circumstances where consent cannot be obtained. Consider what transparency measures will be implemented to inform participants/public about this specific study and the processing of data within this study. eg data protection policies, public notices, publicity campaigns, information leaflets, websites, engagement with representative patient/advocacy groups etc*.* Please provide supporting documentation where possible. |
|  |

*Regulation 3(1)(c)(iv)-(viii)*

|  |
| --- |
| 1. **Identify the technical and organisational measures/arrangements in place to:** 2. **limit access to the personal data being processed, to prevent unauthorised consultation, alteration, disclosure or erasure of personal data** |
|  |
| 1. **log persons who access and process the personal data** |
|  |
| 1. **protect the security of the personal data concerned**   eg encryption techniques, passwords, pseudonymisation techniques, firewalls etc. |
|  |
| 1. **anonymise, archive or destroy personal data once the research study has been completed**   Consider how the data will be further safeguarded by for example, destroying the master list/key, deleting or returning personal data etc. |
|  |
| 1. **Outline any other technical and organisational measures in place, together with processes for testing and evaluating the effectiveness of such measures, to ensure data processing is in accordance with the data protection legislation**([Ref Recital 78/GDPR](https://gdpr-info.eu/recitals/no-78/), [Art 32/GDPR](https://gdpr-info.eu/art-32-gdpr/)) |
|  |

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

|  |
| --- |
| 1. **Provide information on the training in data protection law and practice that has been provided to those individuals involved in carrying out the research** |
|  |

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

|  |
| --- |
| 1. **i) Summarise the findings of the Data Protection Impact Assessment (Max 500 words)**   Please attached a copy of the DPIA. Where there are joint data controllers, a single DPIA will suffice, but the advice of each joint data controller’s DPO must be attached. |
| Copy of DPIA attached  Summary of Assessment: |
| **ii) Please outline or attach the advice of the Data Protection Officer(s) (DPO) regarding the data protection risks of the research study**  Please outline any specific risks highlighted by the DPO, and advice provided to mitigate any risks. |
| Name of DPO #1:  Advice of DPO#1:  Name of DPO #2:  Advice of DPO#2: |
| **iii) Indicate the steps taken to address any risks identified, and/or action taken in relation to advice provided by the DPO**  Please specifically reference any data protection risks identified if data linkage is being carried out and where possible provide details of any consultations undertaken with research participants whose data is being linked*.* |
|  |

**SIGNATURE PAGE TO FOLLOW**

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

DATA CONTROLLER #1

|  |
| --- |
| 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:  Read and acknowledged by an authorised representative within the Organisation of the Applicant:  [this must be an appropriate and competent authority eg Data Protection Officer, Legal counsel]  Name:  Title:  signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: |

DATA CONTROLLER #2

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

**APPENDIX - I**

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

1. **Data Processing:** carrying out the following with personal data: eg accessing, collecting, recording, storing, adapting, pseudonymisation, anonymisation, analysis, linking, combining, sharing, transfers, archiving and destruction ([Ref Art 4(2)/GDPR)](https://gdpr-info.eu/art-4-gdpr/) [↑](#footnote-ref-1)